EPA REGISTRATION NUMBER 71693-1 – VOLUME 2

DP BARCODE: D286702

CASE: 062458 DATA PACKAGE RECORD DATE: 02/04/03
SUBMISSION: S620798 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 010 NEW CHEMICAL SCREENING
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 08/14/02 DUE OUT DATE: 12/12/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286702 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: 11/07/02
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	11/07/02	11/07/02
BRAN: BPPD-IO	11/07/02	11/07/02
SECT: IO	11/07/02	11/07/02
REVR : SBACCHUS	11/07/02	11/07/02
CONTR:	/ /	/ /

ADMIN DUE DATE: 02/05/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Check for package completeness.

* * * DATA PACKAGE EVALUATION * * *

Package still incomplete. Need data waiver request in proper format. Will send packages to contractor pending submission of data waiver request submission

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

I, Michael Braverman, Biopesticide Coordinator
(insert name and title)

of Interregional Research Project No.4 (IR-4) have classified the following documents pertaining to the Active ingredient ***Aspergillus flavus*** **AF36** as indicated in the attached tables.

Signature/title/date Michael Braverman 2/8/02
Biopesticide Coordinator
IR-4 Project

Gave to Mike B. 11/8/02
1) Add new submissions
2) Did NOT include new data?
3) send cover for 825001

Send completed form to:

ATTN: Shanaz Bacchus (7511C)
Biopesticides Pollution Prevention Division
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Index of Documents Submitted

(As of February 8, 2002)

OPP- (Docket #)
***Aspergillus flavus* AF36; Experimental Use Permit 69224-EUP-1; Extension of Temporary tolerance PP# 5E4575**

TITLE: (Title of document)	Author: (Last name, First name)	Document Date	Classification
1. Bibliography (attached)	EPA		
2. Application for Experimental use Permit to Ship and use a Pesticide for perimental Purposes Only Form 8570-17	Cotty, Peter J	1/2/02	B
3. Transmittal Letter and attachments	See Index 1	See Index 1	B
4. Risk Assessment of *Aspergillus flavus* AF36 (Federal register Notice of Filing)	EPA Federal Register Document	To be determined	A
5. Petition for a temporary exemption from the requirement of a tolerance for residues of products containing the active ingredient *Aspergillus* flavus AF36 on cotton in Arizona (PP#5E4575)	See Index 1	See Index 1	Entry Error MB 2/8/02 C See Index 1
6. Specific References to Supporting Data for the pesticide petition from IR-4 for *Aspergillus flavus* AF36, and the Experimental Use Permit (EUP) for (EPA File Symbol 69224-EUP-1, OPP Identifier Number). See references below.	See Attached Bibliography	See Attached Bibliography	C

Michael Braverman 2/8/02

INDEX 1

Index of Documents Submitted

(As of February 8, 2002)

OPP-(Docket #)
Aspergillus flavus AF 36; Experimental Use Permit 69224-EUP-1; Extension of Temporary Tolerance PP#5E4575

TITLE(Title of Document)	Author: (Last name, First name)	Document Date	Classification
3(a) Transmittal Letter(1 page)	Cotty, Peter J.	12-26-01	B
3(b) Letter Concerning Buffer Zones addressed to Phil Hutton	Antilla, Larry	4-21-99	B
3(c) Transmittal Letter (2 pages) for Extension of Temporary Tolerance Exemption on Cotton in Arizona and Expansion to Cover Field Testing in Texas	Braverman, Michael	1-9-02	B
3(d) Letter to Shanaz Bacchus to clarify the purpose of the submission [Note: letter listed in 3(b) was attached to this letter]	Braverman, Michael	1-25-02	B
5(a) Studies submitted in support of Proposed Extension of Tolerance Sections A through G and Attachments	Braverman, Michael	1-9-02	C

TITLE: (Title of document)	Classification
43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 5 Studies. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
763402 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763403 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763404 Cotty, P. (1995) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763405 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C

Michael Braverman 2/8/02

TITLE: (Title of document)	Classification
43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 3 Studies. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972401 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972402 Cotty, P. (1996) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (Aspergillus flavus AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for Apergillus flavus AF36. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 069224EX1	C
43990001 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p. SUBMITTED IN SUPPORT OF: 069224EX1	C

Michael Braverman 2/8/02

TITLE: (Title of document)	Classification
44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Wheat. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 8E5001	C
44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p. SUBMITTED IN SUPPORT OF: 8E5001	C
44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
44626101 Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C

Michael Braverman 2/8/02

TITLE: (Title of document)	Classification
44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C

Michael Braukman 2/8/02

TITLE: (Title of document)	Classification
44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C

Michael Braukman 2/8/02

DP BARCODE: D286705

CASE: 062458 DATA PACKAGE RECORD DATE: 11/07/02
SUBMISSION: S624885 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 100 NC-FOOD/FEED USE
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/07/02 DUE OUT DATE: 05/16/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286705 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	/ /	/ /
BRAN: BPPD-IO	/ /	/ /
SECT: IO	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 03/07/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following for use of Aspergillus flavus atoxigenic strain AF36 for use on cotton to displace the toxigenic strain.
457981-01: Acute pulmonary tox/path in rat. This study was discontinued because of the adverse effects of Tween. The other 2 studies were conducted to replace this study.
457391-01 is an interim report of the next study for acute pulmonary tox/path effects of AF36 in rats.
457982-01: Acute pulmonary tox/path in rat (final study).
Consider the last 2 studies together when assigning a tox category to the active ingredient.
Also review the next submission 457391-04 which reports on hypersensitivity incidents.
If you have any questions, do not hesitate to call me on 703-308-8097
Thanks
Shanaz Bacchus

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D286705

CASE: 062458 DATA PACKAGE RECORD DATE: 11/07/02
SUBMISSION: S624885 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 100 NC-FOOD/FEED USE
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* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286705 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 03/07/03
DIV : BPPD	/ /	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

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If you have any questions, do not hesitate to call me on 703-308-8097
Thanks
Shanaz Bacchus

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

457982-00

8E5001
2E4571

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (IR4)
266A Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

BIOPESTICIDE
PROPOSAL

Sept. 12, 2002

RE: Aspergillus flavus AF-36/Tolerance Exemption for cotton
RAL: Shanaz Bacchus (703)308-8097

Dear Janet:

The undersigned, Dr. Michael Braverman, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, on behalf of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial biopesticide, Aspergillus flavus AF-36.

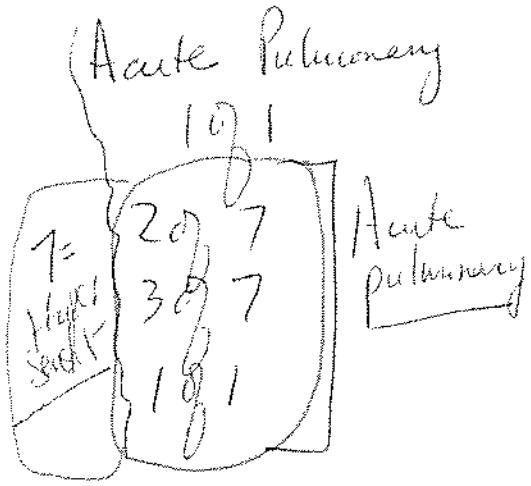
List of Studies Submitted in Support of Proposed Exemption
from the Requirements of a Tolerance for Aspergillus flavus AF-36.

Volume No. and Title

45798201 Volume 1- Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

Note: Although this volume is being submitted individually, it is the third volume pertaining to studies on ASPERGILLUS FLAVUS AF36 ACUTE PULMONARY TOXICITY AND PATHOGENICITY TO THE RAT.

In a previous submission (August 12, 2002) two volumes (Volume 2 of 7 and Volume 4 of 7) were submitted but no MRID numbers have been assigned yet.


Acute Pulmonary
101
207
307
181
Acute pulmonary

Janet Andersen (con't)

List of Supplemental Information Submitted in Support of this Petition:

1. Notice of Filing*
2. Letter of Authorization

* Notice of Filing has already been provided electronically , in Word Perfect format.

Yours very truly,

Michael Bruneau

Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

CC; Peter Cotty, Larry Antilla

NOV 07 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

SOUTHERN REGIONAL RESEARCH CENTER
AGRICULTURAL RESEARCH SERVICES
P.O. BOX 19687
NEW ORLEANS, LA 70179

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 08/14/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

457981-00

Interregional Research Project No. 4
Center for Minor Crop Pest Management

August 12, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (IR4)
266A Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

8E5001
2E6497

BIOPESTICIDE
PROPOSAL

RE: Aspergillus flavus AF-36/Tolerance Exemption for cotton
RAL: Shanaz Bacchus (703)308-8097

Dear Janet:

The undersigned, Dr. W.L. Biehn, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, on behalf of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial biopesticide, Aspergillus flavus AF-36.

List of Studies Submitted in Support of Proposed Exemption
from the Requirements of a Tolerance for Aspergillus flavus AF-36.

Volume No. and Title

Volume 1- Petition Proposing An Exemption from the Requirement of a Tolerance For Sorbitol Octanoate for use in All Food Crops ADMIN

Volume 2 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat 45798101

Volume 3 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report. 45739101

Volume 4- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1. 45798102

Volume 5 - Honey bee Field Study of Aspergillus flavus AF36 in Cotton 45739102

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Janet Andersen (con't)

Volume 6 Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information 45739103

Volume 7 - Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents Amendment No. 1 to MRID 43972402, Amendment No. 2 to MRID 43763404 45739104

List of Supplemental Information Submitted in Support of this Petition:

1. Notice of Filing*
2. Letter of Authorization

* Notice of Filing is also being provided electronically , in Word Perfect format, under separate cover.

Yours very truly,

Michael Braverman

Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

PRECAUTIONARY STATEMENTS

HAZARD TD HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

Establish and adhere to a 400 foot buffer zone for all AF36 treatments with respect to all schools, day care centers, hospitals, nursing homes, health care and other treatment centers where immune compromised individuals may be found. In Texas, do not apply within 20 yards from the edge of a stream channel and select sites where vegetation around the cotton fields is at least 3 inches.

DELETE

AGRICULTURAL USE DIRECTIONS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

DELETE

RE-ENTRY STATEMENT

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of pro-duct needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers: Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses

EXPERIMENTAL USE PESTICIDE

11/8/02

EXPERIMENTAL USE ONLY - NOT FOR SALE TO ANY PERSON OTHER THAN PARTICIPANT OR COOPERATOR OF THE EPA - APPROVED EXPERIMENTAL USE PROGRAM THIS LABEL MUST BE IN THE POSSESSION OF THE USER AT THE TIME OF APPLICATION

FOR USE ONLY AT AN APPLICATION SITE OF A COOPERATOR AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE EXPERIMENTAL PROGRAM -READ SAFETY DIRECTIONS BEFORE OPENING

ASPERGILLUS FLAVUS AF36

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

ASPERGILLUS FLAVUS AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied just prior to first bloom, **ASPERGILLUS FLAVUS AF36** competes with strains of Aspergillus flavus that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop. Thus, **ASPERGILLUS FLAVUS AF36** reduces the quantity of aflatoxin contaminating the crop.

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert ingredients:	0%
Total:	100%

EUP number 69224-EUP-1

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224-EUP-1
EPA Establishment Number 71693-AZ-001

USDA/ARS Southern Regional Research Center
New Orleans, LA 70179

NET CONTENTS: 50 lbs, 1000-3000 lbs

GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply in combination with fertilizers, insecticides, or fungicides.

ACCEPTED

for shipment and use of product for experimental purposes under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.

Permit No. 69224-EUP-1

Issued on 07/02/02

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For application to cotton to control aflatoxin producing strains of *Aspergillus flavus*.

ASPERGILLUS FLAVUS AF36 has been shown to reduce aflatoxin contamination of cottonseed by competitively excluding aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insect[illegible] the same manner that the aflatoxin producing [illegible] present in the field's soil are spread.

DIRECTIONS FOR USE

1. **ASPERGILLUS FLAVUS AF36** may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of **ASPERGILLUS FLAVUS AF36** under the canopy and to minimize delivery of **ASPERGILLUS FLAVUS AF36** to furrows.
3. **ASPERGILLUS FLAVUS AF36** has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of **ASPERGILLUS FLAVUS AF36**.
5. Use 10 lbs of **ASPERGILLUS FLAVUS AF36** per acre [illegible] (3,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. If applying aerially, apply when wind speed is 10 mph or less. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

11/8/02

PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS
Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

AGRICULTURAL USE DIRECTIONS
The pesticide should only be applied when the potential for drift to adjacent environmentally sensitive areas is minimal. May be applied to irrigated cotton fields.

RE-ENTRY STATEMENT
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, longsleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21CMixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

GENERAL USE PRECAUTIONS
Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.
PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.
CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

ASPERGILLUS FLAVUS AF36

FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

ASPERGILLUS FLAVUS AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied just prior to first bloom, **ASPERGILLUS FLAVUS AF36** competes with strains of Aspergillus flavus that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop. Thus, **ASPERGILLUS FLAVUS AF36** reduces the quantity of aflatoxin contaminating the crop.

Active ingredient: *Aspergillus flavus* strain AF36 (3,000 CFU/g)	0.0008%
Wheat seeds	99.9992%
Total:	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For application to cotton to control aflatoxin producing strains of *Aspergillus flavus*.

ASPERGILLUS FLAVUS AF36 has been shown to reduce aflatoxin contamination of cottonseed by competitively excluding aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

1. **ASPERGILLUS FLAVUS AF36** may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of **ASPERGILLUS FLAVUS AF36** under the canopy and to minimize delivery of **ASPERGILLUS FLAVUS AF36** to furrows.
3. **ASPERGILLUS FLAVUS AF36** has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of **ASPERGILLUS FLAVUS AF36**.
5. Use 10 lbs of **ASPERGILLUS FLAVUS AF36** per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT
To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

United States Environmental Protection Agency
Office of Pesticide Programs
Information Resources and Services Division
Information Services Branch

8[redacted]1-02

EPA

ADMINISTRATIVE NO(S).: 8E5001
~~2E6497~~

PM: 20- Janet Andersen

CHEMICAL NO.: _____

The jacket for this action can be requested through the JACKETS system.

DP BARCODE: D288781

CASE: 062458 DATA PACKAGE RECORD DATE: 03/11/03
SUBMISSION: S630863 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 194 ACTN INI BY AGCY-ADDL REQ
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 03/11/03 DUE OUT DATE: 09/07/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288781 EXPEDITE: N DATE SENT: 03/11/03 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	03/11/03	/ /
BRAN: BPPD-IO	03/11/03	/ /
SECT: IO	03/11/03	/ /
REVR : CETSITTY	03/11/03	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 07/29/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please confirm that the justifications for the data waiver requests submitted for the acute health effects studies are acceptable for the Sec. 3c registration of A. flavus AF36 for use in AZ and TX. If there are deficiencies in this request, please state clearly what data/justification must be submitted to satisfy the deficiency.
Thanks,
shawn

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D286708

CASE: 062458 DATA PACKAGE RECORD DATE: 03/11/03
SUBMISSION: S624888 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 152 PROP TEST PROT-NEW BIOL
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/06/02 DUE OUT DATE: 04/05/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286708 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	11/07/02	/ /
BRAN: BPPD-IO	11/07/02	/ /
SECT: IO	11/07/02	/ /
REVR : GTOMIMAT	02/13/03	/ /
CONTR: OAK RIDGE	12/10/02	/ /

ADMIN DUE DATE: 02/20/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following for use of Aspergillus flavus, atoxigenic strain AF36 on cotton in AZ and TX.
457981-01 Tox/path to bobwhite quail
457391-02 Honey bee study of AF36 on cotton
457391-03 AF36 non-target submission to demonstrate that plovers are not in the treatment areas.
Include any adverse effects observed in the trials in your reports.
If you have any questions, do not hesitate to email me at bacchus.shanaz@epa.gov
Thanks
Alan to do secondary on honey bee, Gail to do data waivers and avian inhalation and to coordinate with Joel.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D288782

CASE: 062458 DATA PACKAGE RECORD DATE: 03/11/03
SUBMISSION: S630867 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 157 DATA WAIV REQ-NEW BIOL
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 03/11/03 DUE OUT DATE: 08/08/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288782 EXPEDITE: N DATE SENT: 03/11/03 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	03/11/03	/ /
BRAN: BPPD-IO	03/11/03	/ /
SECT: IO	03/11/03	/ /
REVR : GTOMIMAT	03/11/03	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 06/24/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please determine whether the justifications for waiving ecological effects data are acceptable (Section 2 of this submission). If there are deficiencies in the jsutifications, please state what steps/further action the company needs to take to fulfil data requirments.
Thanks,
shawn

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D288780

CASE: 062458 DATA PACKAGE RECORD DATE: 03/11/03
SUBMISSION: S624888 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 152 PROP TEST PROT-NEW BIOL
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/06/02 DUE OUT DATE: 04/05/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288780 EXPEDITE: N DATE SENT: 03/06/03 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 06/19/03
DIV : BPPD	03/06/03	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	03/06/03	/ /	PROJ DATE: / /
SECT: IO	03/06/03	/ /	
REVR : AREYNOLD	03/06/03	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Please do a secondary review of data for AF36 effects on honeybee in cotton fields. If there are any data deficiencies, describe what data are required to satisfy them.
Thanks.
shawn

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
286708	BPPD-IO/IO	11/07/02	02/20/03	Y	Y	Y

DP BARCODE: D288780

CASE: 062458 DATA PACKAGE RECORD DATE: 03/11/03
SUBMISSION: S624888 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 152 PROP TEST PROT-NEW BIOL
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/06/02 DUE OUT DATE: 04/05/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288780 EXPEDITE: N DATE SENT: 03/06/03 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	03/06/03	/ /
BRAN: BPPD-IO	03/06/03	/ /
SECT: IO	03/06/03	/ /
REVR : AREYNOLD	03/06/03	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 06/19/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please do a secondary review of data for AF36 effects on honeybee in cotton fields. If there are any data deficiencies, describe what data are required to satisfy them.
Thanks.
shawn

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
286708	BPPD-IO/IO	11/07/02	02/20/03	Y	Y	Y

Attached You Will Find an Updated Index for Your Docket:

Docket # OPP-2003-0030	Date Index Sent: MAR 18 2003

TO VIEW THE CONTENTS OF YOUR DOCKET and DOWNLOAD ANY COMMENTS RECEIVED, LOG ONTO EDOCKET AT: intranet.epa.gov/edocket,
Do a "Quick Search" for docket - OPP-2003-0030

OPP-2003-0020 Docket Index

Legacy Identifier: OPP-2002-0093
Title: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

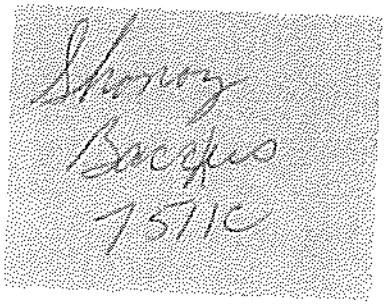
Displaying 1- 9 of 9 Documents Found

Document ID	Date	Type	Title
OPP-2003-0020-0001	02-14-2003	Federal Register	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0002	05-26-1999	Support-Background	Aspergillus Flavus AF36; Pesticides Tolerance Exemption
OPP-2003-0020-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0020-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary exemption from the Requirement of a Tolerance
OPP-2003-0020-0005	12-23-2002	Support-Background	Aspergillus AF36 ai#006456; Pending Section 3 Registration Number 71693-R, Petition 8E5001
OPP-2003-0020-0006	02-19-2003	Public Comment	Comments from a Private Citizen Re:Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0007	03-07-2003	Public Comment	Comments from the Farmers Gin, Inc. Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or orn Food
OPP-2003-0020-0008	03-03-2003	Public Comment	Comments from the Anderson Clayton Corp. Re: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0009	03-03-2003	Public Comment	Comments from the Texas A&M University Agricultural Research & Extension Center Re: Aspergillus flavus AF36

Attached You Will Find an Updated Index for Your Docket:

Docket # OPP-2003-0048	Date Index Sent: MAR 12 2003

TO VIEW THE CONTENTS OF YOUR DOCKET and DOWNLOAD ANY COMMENTS RECEIVED, LOG ONTO EDOCKET AT: intranet.epa.gov/edocket,
Do a "Quick Search" for docket - OPP-2003-0048



Legacy Identifier: OPP-2003-0020
Title: Pesticide Product; Registration Application

Displaying 1- 6 of 6 Documents Found

Document ID	Date	Type	Title
OPP-2003-0048-0001	03- t2-2003	Federal Register	Pesticide Product; Registration Application
OPP-2003-0048-0002	05-26-1999	Support-Background	Aspergillus Flavus Af36; Pesticide Tolerance Exemption
OPP-2003-0048-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0048-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0048-0005	12-23-2002	Support-Background	Aspergillus Flavus AF36 ai#006456 Pending Section 3 Registration Number 71693-R, Petition 8E5001
OPP-2003-0048-0006	02-14-2003	Support-Background	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

FEB 19 2003

Attached You Will Find an Index for Your Docket OPP-2003-0020

TO VIEW THE CONTENTS OF YOUR DOCKET and DOWNLOAD ANY COMMENTS RECEIVED,

LOG ONTO EDOCKET AT:
intranet.epa.gov/edocket
and do a "quick search" for docket - OPP-2003-0020

OPP-2003-0020 Docket Index

Legacy Identifier: OPP-2002-0093
Title: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

Displaying 1- 5 of 5 Documents Found

Document ID	Date	Type	Title
OPP-2003-0020-0001	02-14-2003	Federal Register	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0002	05-26-1999	Support-Background	Aspergillus Flavus AF36; Pesticides Tolerance Exemption
OPP-2003-0020-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0020-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary exemption from the Requirement of a Tolerance
OPP-2003-0020-0005	12-23-2002	Support-Background	Aspergillus AF36 ai#006456; Pending Section 3 Registration Number 71693-R, Petition 8E5001

Conference Call with EPA Thursday, March 13th, 2003 at 2:30 PM EST

The following ten individuals are potential participants in conference call from outside EPA:

✓ Dr. Phil Wakelyn, Senior Scientist, National Cotton Council, Washington, DC PW
✓ Dr. Michael Braverman, Biopesticide Manager, IR-4, Rutgers University, New Brunswick, NJ
✓ Larry Antilla, Staff Director, Arizona Cotton Research and Protection Council, Phoenix, AZ
✓ Dr. Peter J. Cotty, Research Plant Pathologist, USDA, ARS, SRRC, New Orleans, LA
✓ Dr. Jane F. Robens, National Program Leader, USDA, ARS, Beltsville, MD
Jeff Nunley, Executive Vice President, South Texas Cotton and Grain Association, Victoria, TX
✓ Craig Shook, Chairman of the Board, South Texas Cotton and Grain Association, Victoria, TX
✓ Clyde Sharp, President, Arizona Cotton Growers Association, Phoenix Arizona
~~Hollis Sullivan~~, Manager, Valley Cooperative Oil Mill, Harlingen, Texas
Bobby Kuhn

AT EPA CM2

BPPD

" Shanaz Bacchus 703-308-8097
" Dennis Szuhay 703-305-6098
" Jim Downing 703-308-9071
Phil Hutton 703-308-8260

Teleconference – AF36 [redacted] 3/13/03

Desert valleys – CA.

Gulf coast – Different microbial populations

5 Strains same in TX, AZ.

AZ + TX humid in canopies – mature bolls – high nighttime T°.

HI T°, hi humidity similar to TX

* Dausman Hall paper – bridging to TX

Product not public health pesticide – doesn't affect aflatoxin level – after treatment

0 – 20 ppb / cattle – % cotton crop.

Exposure to cattle doesn't change

Measure seed / milk – FDA

Economic not health issues.

May 1 – Cotton TX knee-hi.

Economic

lbs seed –

Cost $1m. – contamination.

2000 A – TX. – Larry – budget –

expansion of program.

Clyde Sharp. AZ: clean

Mike

Look at

May 1

Condition on review of data –

Craig Shook

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

AGRICULTURAL USE DIRECTIONS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields.

RE-ENTRY STATEMENT

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, long-sleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C. Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

ASPERGILLUS FLAVUS AF36

FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

~~FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED~~

ASPERGILLUS FLAVUS AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied just prior to first bloom, **ASPERGILLUS FLAVUS AF36** competes with strains of Aspergillus flavus that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop. Thus, **ASPERGILLUS FLAVUS AF36** reduces the quantity of aflatoxin contaminating the crop.

Active ingredient: *Aspergillus flavus* strain AF36 (3,000 CFU/g)	0.0008%
Wheat seeds	99.9992%
Total:	100%

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

New Label

NET CONTENTS: 50 lbs, 1000-3000 lbs

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For application to cotton to control aflatoxin producing strains of *Aspergillus flavus*.

ASPERGILLUS FLAVUS AF36 has been shown to reduce aflatoxin contamination of cottonseed by competitively excluding aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

1. **ASPERGILLUS FLAVUS AF36** may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of **ASPERGILLUS FLAVUS AF36** under the canopy and to minimize delivery of **ASPERGILLUS FLAVUS AF36** to furrows.
3. **ASPERGILLUS FLAVUS AF36** has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of **ASPERGILLUS FLAVUS AF36**.
5. Use 10 lbs of **ASPERGILLUS FLAVUS AF36** per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

Kimberly Smith
05/17/02 01:35 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Confirmation of (RPAS) Docket #

This note is to confirm the docket number that was given to you on 5/15
If the Number is **CORRECT**, ***please DON'T respond***

OPP-2002-0093

Kimberly Smith/ASRC
Task Order Manager
EPA Office of Pesticide Programs
Public Docket Manager
Phone: 703-305-6434

Docket

Comments
EUP

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OFFICE OF PESTICIDE PROGRAMS

PUBLIC RECORD CERTIFICATION

This is to certify that the materials assembled as the official public rulemaking record for the **Federal Register** docket identified as OPP-2002-00983
(Insert Docket # and Title)
Aspergillus flavus AF36: Amendment Temporary Exemption from the Requirement of a Tolerance (Final Rule)
has been reviewed by the Public Information and Records Integrity Branch.

The information is complete, and has been assembled in an useable form to

support the document being published in the Federal Register.

Cross-Reference File: PF-1076: Notice of Filing a Pesticide Petition to Amend an Existing Tolerance for a certain Microbial Pesticide in/on Food (Aspergillus flavus AF36)
(Insert Docket # and Title of Cross-Reference File)

Dated: 5/15/02

Shana Baccch, Chemist
OPP/BPPD
Program Office

Public Information and Records
Integrity Branch (OPP Docket)

Shanaz Bacchus

03/20/02 08:35 AM

To: Gail Tomimatsu/DC/USEPA/US, John Kough/DC/USEPA/US,
cc: Phil Hutton/DC/USEPA/US
cc:
Subject: RE: AF36 progress/EUP TX

Some answers re TX
Shawn
----- Forwarded by Shanaz Bacchus/DC/USEPA/US on 03/20/02 08:35 AM -----

Mike Braverman
<braverman@AESDP.RUTGERS.EDU>

03/19/02 07:04 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: RE: AF36 progress

Shanaz

I have pasted Peter's responses which follow the numbered questions from our last discussion below. I would have to consult with him about potential submission dates for the avian and mammalian study. I have the Bee study, and beleive the avian is complete, but is awaiting the completed reports. The mammalian is still being done so I don't wan't to speculate on that. I could send the bee study in a few weeks. I would guess the avian study could be submitted in a month or so but Peter would be a better judge of that. In addition, I have other packages that I am working on.

Hope these answers of Peter's help.

The following are my responses to the inquiry from EPA.

1. Are the cultural or environmental conditions in AZ and TX similar enough so
that you are sure that infection will occur at the same time.

The time of infection differs among fields and between years in Arizona and we expect this to be the same in Texas. The industry has given us an extensive database concerning the incidences of toxin in the cottonseed crop in South Texas and there are several aspects that are similar to what we see in Arizona. The important element for success of our strategy is that the A. flavus community declines during the winter months and increases rapidly during the warm months This is similar to what we see in Arizona.

2. Are the soil conditions similar enough between AZ and TX such that there is
similar prevelance of aflatoxin producing organisms in TX.

The soils vary considerably throughout Arizona and South Texas. However, areas with high aflatoxin contamination in the two areas have in common a high prevalence of the high aflatoxin producing S strain of A. flavus. This surprised us because the S strain was initially described from Arizona. However, in portions of South Texas the S strain is just as common as in the areas of Arizona with the highest incidences of S strain. A major goal of treatments is to displace the highly toxigenic S strain isolates.

3. In Texas, what is the proximity of cotton to other crops that would be treated with AF36 and is there any risk-host range associated with the

application. I pointed out there are other crops that would benefit such as corn.

The primary crop rotation in the treatment areas is cotton-corn-sorghum. All these crops have been grown in the treatment areas of Arizona over the past three years. There are high quantities of A. flavus throughout the environment in agricultural fields of South Texas. The A. flavus strain proposed for use is native throughout the area. Thus the crops are continually exposed to A. flavus already.

4. Repeated the requests for TX county maps.

We are working with the South Texas Boll Weevil Eradication Foundation to develop the requested maps. We anticipate that these should be completed prior to treatment. I have forwarded your concern to the involved parties.

5. Are any endangered species present in the TX counties.

I am certain there must be some endangered species. We do not have details on this aspect. However, the same rational as that used in Arizona applies. A. flavus occures at high levels throughout the area and thus species are already exposed to significant levels of A. flavus. Aflatoxin producers are common on crops and in soils throughout the area. Displacement of the aflatoxin producers with a strain that does not produce aflatoxins should provide a benefit to endangered species. The atoxigenic strain already is common throughout the proposed treatment area. Toxicity studies in insects, mammals, and birds suggest there is no pathogenicity or toxicity concern.

6. Can you differentiate between L and S strains in the soil as per letter of Dec 14 , 1999.

Yes. This is done routinely as it has been done during the Experimental Program in Arizona.

7. What's the status of the tox work that is going on.

We have completed the Bee, Avian pulmonary and Mammalian pulmonary studies requested by EPA. The results suggest there are no pathogenicity or toxicity problems with Aspergillus flavus AF36. We are waiting for the formal reports from the toxicology laboratory. We anticipate meeting with EPA in the next few months to review the results and discuss the section 3 registration for Arizona.

I hope these responses are sufficient. I leave for Texas around 3 PM and will meet with some of our industry partners over the next week as we take soil samples throughout the South Texas production areas.

We all greatly appreciate the continued assistance of yourself and IR-4.

Sincerely,

--Peter.

Peter J. Cotty, Ph.D.
Research Plant Pathologist
Southern Regional Research Center
Agricultural Research Service

PUBDIR="/epahome/images/"

PUBDIR="/epahome/images/"

Federal Register Document

Related Material

- Other Related Documents

[Federal Register: June 30, 1999 (Volume 64, Number 125)] [Rules and Regulations] [Page 35049-35051] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr30jn99-27]

ENVIRONMENTAL PROTECTION AGENCY 40 CFR Part 180 [OPP-300860A; FRL-6087-3] Aspergillus flavus AF36; Exemption from Temporary Tolerance, Technical Amendment AGENCY: Environmental Protection Agency (EPA). ACTION: Final rule; Technical amendment.

SUMMARY: EPA is issuing a technical amendment to the expiration date for an exemption from temporary tolerance regulation for Aspergillus flavus AF36 that published in the Federal Register on May 26, 1999 (64 FR 28371) (FRL-6081-2). This amendment corrects the expiration date for the exemption from temporary tolerance for residues of the atoxigenic Aspergillus flavus AF36 on cotton grown in certain Counties in Arizona to December 30, 2001, in order to allow clearance of the treated food/ feed commodities through the channels of trade.

DATES: This regulation is effective June 30, 1999. You may submit an objection [[Page 35050]] or request a hearing as specified in Unit IV. of the ``SUPPLEMENTARY INFORMATION'' section of this document. Any objection or hearing request must identify docket control number [OPP-300860A], and must be received by the EPA Hearing Clerk on or before August 30, 1999. FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703-308-8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION: I. Does this Action Apply to Me? You may be affected by this action if you are a cotton producer in certain counties of Arizona (NAICS 11192). If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the ``FOR FURTHER INFORMATION CONTACT'' section.

II. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents? 1. Electronically. You may obtain electronic copies of this document and various support documents from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ``Laws and Regulations'' and then look up the entry for this document under the ``Federal Register - Environmental Documents.'' You can also go directly to the ``Federal Register'' listings at http://www.epa.gov/ fedrgstr/. 2. In person. The Agency has established an official record for this action under docket control number [OPP-300860A]. The official record consists of the

documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in tbe docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703-305-5805.

III. What Does this Technical Correction Do? This technical correction amends the expiration date for an exemption from temporary tolerance for residues of atoxigenic Aspergillus flavus AF36 on cotton in Arizona treated in accordance with the Experimental Use Permit 69224-EUP-1. This temporary exemption from a tolerance was established on May 26, 1999 (64 FR 28371) (FRL-6081-2) in response to a petition submitted by the Interregional Research Project Number 4 (IR-4). Specifically, IR-4 requested an exemption from temporary tolerance for residues of Aspergillus flavus AF36 on cotton in certain counties in Arizona as specified in the Experimental Use Permit 69224-EUP-1 under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The Notice of Petition appeared in the Federal Register on February 19, 1999 (64 FR 8358) (FRL-6057-3). At the time of the petition, as presented in the notice of petition as published on February 19, 1999, IR-4 specifically requested that the exemption from temporary tolerances be established for residues of this microbial pesticide until December 30, 2001, to allow the treated cotton to clear the channels of trade. (See 64 FR 8358, at 8358). Inadvertently, the expiration date appeared as December 30, 2000 in the May 26, 1999 final rule. However, in granting the request contained in the petition, the Agency intended to grant the expiration date specifically requested by IR-4. This document corrects the expiration date that appears in the May 26, 1999 final rule, by changing December 30, 2000 to December 30, 2001 in the regulation. This correction to the exemption from a temporary tolerance is subject to the objection procedures in FFDCA section 408(g)(2) and 40 CFR part 178.

IV. Why Is this Technical Correction Issued as a Final Rule? EPA is publishing this action as a final rule without prior notice and opportunity to comment because the Agency believes that providing notice and an opportunity to comment is unnecessary and would be contrary to the public interest. As explained above, the correction contained in this action will simply correct the expiration date for the exemption from temporary tolerances established for residues of this microbial pesticide to allow the treated cotton to clear the channels of trade. EPA therefore finds that there is ``good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) to make this amendment without prior notice and comment. For the same reasons, EPA also finds that there is ``good cause'' under FFDCA section 408(e)(2) to make this minor modification to the exemption from tolerance without notice and comment.

V. Do Any of the Regulatory Assessment Requirements Apply to this Action? No. This final rule does not impose any new requirements. It only implements a technical correction to the Code of Federal Regulations (CFR). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled Regulatory Planning and Review (58 FR

51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). In addition, since this action is not subject to notice-and-comment requirements under the Administrative Procedure Act (APA) or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.). EPA's compliance with these statutes and Executive Orders for the May 26, [(Page 35051]] 1999 final rule, which established the exemption from temporary tolerance for residues of the atoxigenic Aspergillus flavus AF36 on cotton grown in certain Counties in Arizona, is discussed in the preamble for the final rule (64 FR 28371, at 28373).

VI. Will EPA Submit thie Final Rule to Congress and the Comptroller General? Yes. The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This is not a ``major rule'' as defined by 5 U.S.C. 804(2). List of Subjects in 40 CFR Part 180 Environmental Protection, Administrative Practice and Procedure, Agricultural Commodities, Pesticides and Pests, Reporting and Recordkeeping Requirements. Dated: June 10, 1999. Kathleen D. Knox, Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs. Therefore, 40 CFR chapter I is amended as follows: PART 180--[AMENDED] 1. The authority citation for part 180 continues to read as follows: Authority: 21 U.S.C. 321(q), 346(a) and 371. Sec. 180.1206 (Amended] 2. Section 180.1206 is amended by revising the date in the last sentence therein to read ``December 30, 2001''. [FR Doc. 99-16546 Filed 6-29-99; 8:45 am] BILLING CODE 6560-50-F

[Federal Register: March 25, 2002 (Volume 67, Number 57)]
[Notices]
[Page 13628-13630]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr25mr02-61]

ENVIRONMENTAL PROTECTION AGENCY
[PF-1076; FRL-6827-8]

Notice of Filing a Pesticide Petition to Amend An Existing Tolerance for a Certain Microbial Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: This notice announces the amendment of a pesticide petition proposing the revision of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-1076, must be received on or before April 24, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the SUPPLEMENTARY INFORMATION. To ensure

[[Page 13629]]

proper receipt by EPA, it is imperative that you identify docket control number PF-1076 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus,Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8097; e-mail address:
HREF="mailto:bacchus.shanaz@epa.gov">bacchus.shanaz@epa.gov</A>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	Examples of NAICS codes	potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <A HREF="http://www.epa.gov/">http://www.epa.gov/</A>. To access this document, on the Home Page select ``Laws and Regulations'' and then look up the entry for this document under the ``Federal Register--Environmental Documents.'' You can also go directly to the Federal Register listings at <A HREF="http://www.epa.gov/fedrgstr/">http://www.epa.gov/fedrgstr/</A>.

2. In person. The Agency has established an official record for this action under docket control number PF-1076. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy.,

Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1076 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. Electronically. You may submit your comments electronically by e-mail to: <A HREF="mailto:opp-docket@epa.gov">opp-docket@epa.gov</A>, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-1076. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you

arrived at the estimate that youprovide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received an amended pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide microbial in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains

[[Page 13630]]

data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:March 14, 2002.
Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4

PP 5E4575

EPA has received an amended pesticide petition PP 5E4575 from Interregional Research Project Number 4 (IR-4), proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.1206 to extend the temporary exemption from tolerance for residues of the non-aflatoxin-producing microbial pesticide

[Federal Register: May 23, 2001 (Volume 66, Number 100)]
[Rules and Regulations]
[Page 28383-28386]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr23my01-13]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301124; FRL-6781-7]
RIN 2070-AB78

Aspergillus flavus AF36; Extension of Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a temporary exemption from the requirement of a tolerance for residues of the biological Aspergillus flavus AF36, (A. flavus) a non-aflatoxin producing strain of A. flavus, on cotton when applied or used as aerial pre-bloom applications to cotton in specified counties of Arizona. The Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390, submitted an amended petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting the temporary exemption. This regulation eliminates the need to establish a maximum permissible level for residues of Aspergillus flavus AF36. The temporary tolerance exemption will expire on December 30, 2003.

DATES: This regulation is effective May 23, 2001. Objections and requests for hearings, identified by docket control number OPP-301124, must be received by EPA on or before July 23, 2001.

ADDRESSES: Written objections and hearing.requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the

4

mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Additionally, section 408(b)(2)(D) requires that the Agency consider ``available information concerning the cumulative effects of a particular pesticide's residues and ``other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

The fungal agent is applied prebloom to the soil of treated cotton fields. When conditions are appropriate, the AF 36 spores land on the cotton plant and germinate to displace the naturally occurring toxigenic strain. No adverse effects were reported in the annual reports which the registrant submitted as required in the EUP.

This extension of the exemption from the requirement of a temporary tolerance is associated with an extension of an Experimental Use Permit (EUP, EPA Reg. No. 69224-EUP-1). This extension of the EUP will allow aerial application of A. flavus AF36 in the following counties of Arizona: Yuma (3,300 acres), Maricopa (13,150 acres), Mohave (1,700 acres) and Pinal (1,850 acres). This final rule extends the temporary exemption from a tolerance for residues of Aspergillus flavus AF36 on cotton until December 30, 2003.

Of the strains of A. flavus found naturally in Arizona, this atoxigenic strain comprises about 15% of the natural microbial population in the soil, as opposed to the predominant S or toxigenic S strain.

Summaries of the toxicological profile and other relevant manufacturing and health effects data, to comply with the guideline requirements of the Food Quality Protection Act of 1996, were reported in the Federal Register publication of the final rule of May 26, 1999, extending the temporary tolerance exemption. Based on the previously submitted data outlined in the final rule, there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to A. flavus AF36 from the limited use pattern of this experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

The Agency continues to require that the pesticide must not be applied within a boundary of 400 feet of residential areas, schools, daycare and health care facilities and hospitals to minimize exposure to human adults, infants and children.

Data have been submitted to demonstrate that this strain excludes the aflatoxin-producing strain when it is applied prior to flowering. Thus, the proposed use is not likely to result in appreciable increases in the long-term population of A. flavus on the crop beyond naturally

HREF="http://www.epa.gov/">http://www.epa.gov/</A>. To access this document, on the Home Page select ``Laws and Regulations,'' ``Regulations and Proposed Rules,'' and then look up the
entry for this document under the ``Federal Register--Environmental Documents.'' You can also go directly to the Federal Register listings at <A HREF="http://www.epa.gov/fedrgstr/ ">http://www.epa.gov/fedrgstr/</A>. A frequently updated electronic version of 40 CFR part 180 is available at <A
HREF="http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html">http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html</A>, a beta site currently under development.

2. In person. The Agency has established an official record for this action under docket control number OPP-301124. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the Federal Register of May 26, 1999 (64 FR 28371) (FRL-6081-2), EPA issued a final rule pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) establishing a temporary exemption from the requirement of a tolerance for residues of A. flavus AF36 on cotton grown in 5 counties in Arizona (40 CFR 180.1206). This final rule included a summary of the Agency's assessment of the health effects data submitted in support of the extension of the temporary tolerance exemption. The temporary exemption from tolerance was extended until December 2001 (64 FR 35049, June 30, 1999) (FRL-6087-3) to allow for passage of the treated commodities through the channels of trade.

Comments submitted to the Agency regarding the use of this competitive fungal agent were by the cotton growers in the region who were all in favor of the extension of the exemption from the temporary tolerance. Both the toxigenic and atoxigenic strains are naturally occurring in Arizona. The growers were of the opinion that this technology is likely to reduce the high levels of the naturally occurring, toxin-producing strain of A. flavus by displacement. No adverse effects were reported in the yearly annual reports of the Experimental Use Permit, and in some instances aflatoxin levels of cotton seed were reduced in treated cotton.

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ``safe.'' Section 408(c)(2)(A)(ii) defines ``safe'' to

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occurring levels.

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Furthermore, there is no expectation of cumulative effects with other pesticides, because this is the only registered experimental microbe in this genus.

As in the earlier EUP, the Agency requires that applicators and other handlers must wear gloves, a dust/mist filtering respirator with NIOSH approval prefix N-95, R-95 or P-95, long sleeved shirt and long pants, and shoes plus socks to mitigate potential worker exposure.

The Food and Drug administration (FDA) regulates the levels of aflatoxin in cotton seed meal and other commodities associated with the production of cotton. Treated cotton and its by products are screened for aflatoxin prior to introduction into the channels of commerce. FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb) or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb to be used for feeding beef cattle.

C. Codex Maximum Residue Level

An exemption from temporary tolerance for residues of A. flavus isolate AF36 on cotton (40 CFR 180.1206) is currently in effect in conjunction with an Experimental Use Permit (61 FR 30235, June 14, 1996, and extended to expire in December 2001) (FRL-5377-6).

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301124 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before july 23, 2001.

1. Filing the request. Your objection must specify the specific provisions in the regulation that

2.

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301124 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-8097; and e-mail address: <A HREF="mailto:bacchus.shanaz@epa.gov ">bacchus.shanaz@epa.gov</A>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	Examples of Potentially NAICS Affected Entities
Industry	111 Crop production 112 Animal production 311 Food manufacturing 32532 Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of

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entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <A

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you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ``Tolerance Petition Fees."

EPA is authorized to waive any fee requirement``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at <A HREF="mailto:tompkins.jim@epa.gov">tompkins.jim@epa.gov</A>, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301124, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: <A HREF="mailto:opp-docket@epa.gov">opp-docket@epa.gov</A>. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule extends a temporary exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any

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information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the [tolerance] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ``meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ``Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

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For these same reasons, the Agency has determined that this rule does not have any ``tribal implications'' as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ``meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ``Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.''

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 9, 2001.
Janet L. Anderson,
Director, Biopesticide and Pollution Prevention Division.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1206 is revised to read as follows:

Sec. 180.1206 Aspergillus flavus AF36.

Aspergillus flavus AF36 is temporarily exempt from the requirement of a tolerance in or on cotton when used on cotton in Arizona in accordance with the Experimental Use Permit 69224-EUP-1. The temporary exemption from a tolerance will expire on December 30, 2003.

[FR Doc. 01-12900 Filed 5-22-01; 8:45 am]

Federal Register Document

Related Material

- Other Related Documents

[Federal Register: May 26, 1999 (Volume 64, Number 101)]
[Rules and Regulations]
[Page 28371-28374]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr26my99-10]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300860; FRL-6081-2]
RIN 2070-AB78

Aspergillus flavus AF36; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency [EPA].

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biological Aspergillus flavus AF36, a non-aflatoxin producing strain of A. flavus, on cotton when applied/used as an antifungal agent. The Interregional Research Project Number 4 [IR-4) submitted an amended Pesticide Petition (PP) 5E4575 to EPA under the Federal Food, Drug, and Cosmetic Act [FFDCA), and also to comply with the Food Quality Protection Act of 1996 (FQPA] requesting an extension of the temporary exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Aspergillus flavus AF36. The temporary exemption from the requirement of a tolerance will expire on December 30, 2000.

DATES: This regulation is effective May 26, 1999. Objections and requests for hearings must be received by EPA on or before July 26, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300860], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ``Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing

requests filed with the Hearing Clerk identified by the docket control number, (OPP-300860], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300860). No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-8097, e-mail: bacchus.shanaz @epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 19, 1999 (64 FR 8358) (FRL-6081-2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996 (Pub. L. 104-170) announcing the filing of a pesticide tolerance petition by the IR-4, New Jersey Agricultural Experiment Station, Technology Center of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The notice included a summary of the petition prepared by the petitioner, IR-4. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of Aspergillus flavus AF36 in/on cotton in Arizona.

Comments submitted to the Agency regarding the proposed use of the antifungal agent were by the cotton growers in the region who were all in favor of the extension of the temporary exemption from the tolerance. Both the toxigenic and atoxigenic strains are naturally occurring in Arizona. The growers were of the opinion that this technology is likely to reduce the high levels of the naturally occurring, toxin-producing strain of A. flavus by displacement.

I. Background and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ``safe.'' Section 408(c)(2)(A)(ii) defines ``safe'' to mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...''. Additionally, section 408 (b)(2)(D) requires that the Agency consider ``available information'' concerning the cumulative effects of a particular pesticide's residues and ``other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide

through food, drinking water, and through other exposures that occur as a result of pesticide us in residential settings.

This extension of the temporary exemption from the requirement of a tolerance is associated with an extension of an Experimental Use Permit (69224-EUP-1), published in the Federal Register of February 14, 1996, (61 FR 5771) (FRL-5347-5), which was granted to the Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service (USDA ARS), 1100 Robert E. Lee Blvd., New Orleans, LA 70179-0687 on May 28, 1996 and expires May 20, 1999. Approximately 1,120 acres of cotton in Yuma County, Arizona, were treated at a rate of 10 pounds (lbs.) of the pesticide per acre over the 3-year period. A temporary exemption from the requirement of a tolerance was established in connection with this EUP as published in the Federal Register of June 14, 1996, (61 FR 30235) (FRL-5377-6). No adverse effects were reported in the annual reports which the registrant submitted as required in the EUP.

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USDA ARS has amended the EUP and extended treatment to a total of 20,000 acres of commercial cotton fields in 5 of the 15 counties in Arizona. The aerial applications are to be made in the following counties: Yuma (3,000 A), LaPaz (1,000 A), Maricopa (9,000 A), Mohave (1,000 A) and Pinal (6,000 A). The antifungal agent is applied prebloom to the soil of treated cotton fields, where the mycelia germinate to displace the naturally occurring toxigenic strain.

Of the strains of A. flavus which abound naturally in Arizona, this atoxigenic L strain comprises 15% of the natural microbial population in the soil, as opposed to the predominant S or toxigenic S strain.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicological profile in support of the extension of the temporary exemption from a tolerance of the residues of the atoxigenic (non-toxin producing) A. flavus AF36 demonstrates that the LD<INF>50</INF> of A. flavus AF36 is greater than 5,000 milligrams/kilograms (mg/kg). No adverse clinical effects were observed after 14 days in rats treated by gavage with the microbial antifungal agent and no abnormalities or adverse effects were observed in any of the rats upon autopsy.

Studies were not conducted to evaluate the potential of the active ingredient as an agent linked to genotoxicity, or reproductive, developmental, subchronic or chronic effects, because the researchers have worked with the proposed microbial antifungal agent for several years in laboratory and field settings with no adverse effects. Also, the organism is a naturally occurring, ubiquitous microbe.

III. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to A. flavus AF36 from the limited use pattern of the experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

A. Dietary Exposure

1. Food. Application of the microbial pesticide prebloom in the cultural practice precludes the potential for direct residues of A. flavus per se to remain on the treated cotton. The proposed strain of A. flavus, AF36, is atoxigenic, i.e. not producing aflatoxin. Only the seed of the treated commodity, cotton, is likely to be processed as food for cottonseed oil. Residues of A. flavus AF36 or its metabolites are likely to be removed from cotton seed oil during this processing. Moreover, the applications are proposed for 5 of the 15 counties of Arizona only, on 3-7% of the total cotton, thus minimizing any potential dietary exposure. The Food and Drug Administration (FDA) regulates the levels of aflatoxin in cotton seed meal and other commodities associated with the production of cotton. Cottonseed is monitored for aflatoxin content during the ginning process, and all cotton seed from these experiments will be closely monitored for aflatoxin content as part of the experimental program. On the basis of the preceding discussion, dietary exposure to the treated commodity is likely to be minimal to human adults, infants and children. exposure to immunocompromised human adults, infants and children. Moreover, the application of the microbial pesticide to specific counties during the EUP represents application to approximately 3-7% cultivated areas in these counties, thus minimizing exposure.

1. Dermal exposure. Non-occupational dermal exposure and risk to adults, infants and children are not likely if the pesticide is used as labeled. The antifungal agent is a naturally occurring microbe to be applied to the soil of cotton fields prebloom. It is ubiquitous in the environment. If the microbe exhibits dermal sensitizing properties which is associated with this genus of fungi, the boundaries and the large particle size of the spores are likely to maintain distribution near treated areas thus protecting nearby at-risk populations. Based on the low toxicity potential as evidenced by the data submitted, the microbial pesticide active ingredient is likely to pose a minimal to non-existent hazard if used as labeled.

2. Inhalation exposure. Based on the large spore size of AF36, and on the method of application to the soil of cultivated cotton fields prebloom with set boundaries, non-occupational inhalation exposure and risk to human adults, children and infants are likely to be minimal.

IV. Cumulative Effects

There are no other registered products containing Aspergillus flavus isolate AF36 or any other isolates (strains) of the microbial active ingredient. Moreover, data submitted to the Agency demonstrate that this strain does not produce aflatoxin on the crop or in artificial media in the lab. Data submissions also show that this strain has been shown to exclude the aflatoxin-producing strain when it is applied prior to flowering. Thus, the proposed use is not likely to result in appreciable increases in the long-term population of A. flavus on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

V. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when A. flavus AF36 is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply. The label will require applicators and other handlers to wear gloves, a dust/mist filtering respirator with National Institute of Occupational Safety and Health (NIOSH) approval prefix N-95, R-95 or P-95, long sleeved shirt and long pants, and shoes plus socks so worker exposure should not be a problem. Label language

reflecting potential dermal sensitization is also required.

VI. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on

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the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

Starter cultures are screened on the basis of vegetative incompatibility with the toxigenic strain, as well as for aflatoxin by standard procedures, which allow a zero tolerance for aflatoxin production. A. flavus AF36 does not demonstrate vegetative compatibility with the toxigenic S strain and has never been found to produce aflatoxin. According to the data submissions human pathogens are also within regulatory levels.

Treated cotton and its byproducts are screened for aflatoxin prior to introduction into the channels of commerce. FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb) or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb to be used for feeding beef cattle.

C. Codex Maximum Residue Level

An exemption from temporary tolerance for residues of Aspergillus flavus isolate AF36 on cotton is currently in effect in conjunction with an Experimental Use Permit published in the Federal Register of June 14, 1996 (61 FR 30235).

VII. Objections and Hearing Requests

The new section 408(g) of the FFDCA provides essentially the same process for persons to ``object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 26, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the ``ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance

objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300860] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ``ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993]. This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28,

1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority

[[Page 28374]]

Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the [tolerance/exemption] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ``to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ``to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq. , as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 14, 1999.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division
Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1206 is added to subpart D to read as follows:

Sec. 180.1206 Aspergillus flavus AF 36; Exemption from the requirement of a tolerance.

Aspergillus flavus AF 36 is temporarily exempt from the requirement of a tolerance in/on cotton when used on cotton in Arizona in accordance with the Experimental Use Permit 69224-EUP-1. The temporary exemption from the requirement of a tolerance will expire on December 30, 2000.

[FR Doc. 99-13192 Filed 5-25-99; 8:45 am]
BILLING CODE 6560-50-F

12/OPP# PF-1076

April 15, 2002

(3PP)

RECEIVED
APR 15 2002
OPP PUBLIC DOCKET

RE: Docket #PF-1076

TO: Office of Pesticide Programs
U.S. Environmental Protection Agency

Texas annually harvests over 4 million bales of cotton. Due to environmental conditions, several production regions face perennial problems from aflatoxin contaminated cottonseed. These regions include central Texas (Blackland Prairie and Bottomlands) which produces about 227,000 bales, the south Texas region (Upper Gulf Coast and Coastal Bend) which generates over 687,000 bales, and the Rio Grande Valley area which generates over 243,000 bales. Together these areas support the production of over 1.1 million bales.

According to information provided by the "Office of the State Chemist", cottonseed from these three regions will generally test positive for aflatoxin, and between 15 to 80% of the cottonseed will exceed 20 ppb. As an example, in 1997 and 1998 over 80% of the cottonseed from these regions tested greater than 20 ppb, and in 2001 less than 15% exceeded 20 ppb. When aflatoxin levels in cottonseed exceed the 20 ppb limit, the value of the seed is severely discounted (in most cases by greater than 50%), translating into several million dollars lost to producers and the cottonseed industry. Moreover, due to extremely low prices for cotton lint in current and near-future markets, any discounts in cottonseed value further reduces profitability at the farm level.

The use of atoxigenic strains of *Aspergillus flavus* have proven to be very effective in combating aflatoxin problems in Arizona, and in 2002 20,000 acres will be included in Experimental Use Permit (EUP) trials using the AF36 strain. To date, more than 40,000 cumulative acres have been treated in Arizona with no reported adverse effects. Multi-year air sampling studies have demonstrated that the atoxigenic strain (AF36) has displaced the aflatoxin producing strains with no increase in total fungus in the environment.

Recent research conducted in the Coastal Bend region of Texas in 2000 and 2001 with the AF36 strain has also been very successful. However, these studies were limited to small acreages. Consequently, it is critical to the future success of the project to expand this effort to include an EUP for AF36 in the south Texas region. Based on previous research in Arizona and Texas, and the success of the area-wide program in Arizona, the granting of this EUP for AF36 in south Texas will serve as a major step in reducing aflatoxin problems in Texas cottonseed. I strongly support the EUP for AF36 and urge the EPA to grant its approval.

Respectfully,

Robert G. Lemon
Associate Professor
and Extension Agronomist – Cotton
Department of Soil and Crop Sciences
Texas A&M University
College Station, Texas 77843-2474
r-lemon@tamu.edu

14 /OPP-PF-1076

Comments, identified by docket control number PF-1076

27PP

To whom it may concern,

APR 23 2002

I have several concerns about the science of this approach and I respectfully ask that the science be carefully and thoughtfully re-evaluated before a permanent tolerance is considered. I am attaching two documents that illustrate my concerns. My major concern is whether the science in any crop really suggests that this is a viable approach that a farmer can use. The FDA guide-lines for aflatoxin in crops varies with use. Dr. Peter Cotty in his patent presents his data in micrograms per gram of cottonseed and the normal way that aflatoxin concentrations are expressed is in micrograms per kilogram of product. The difference between these is the first is in parts per million and the second is in parts per billion. When I carefully read the patent I come the conclusion that Dr. Cotty shows that there is a one in three chance that a farmer might end up with a marketable lot of cottonseed. The data on peanuts and corn that has been published certainly shows a reduction in aflatoxin, but the reduction seems to have little practical significance in terms of marketing the crop. I just wonder whether there will ever be a biological control A. flavus or A. parasiticus formulation that will in fact help improve the marketability of the affected crop. My second concern is about the biology of the fungus. A. flavus is recognized as a pathogen on plants, insects and mammals and perhaps other organisms. The striking feature of the fungus is that it rarely successfully invades healthy tissue, but can invade stressed tissue.

When pathogenicity studies are conducted should one use immunosuppressed individuals and organisms , ones treated with steroids or other environmental stresses? It seems to me that we will be doing the United States farmer and consumer little good if the science, the pathogenicity risks, the allergy risks and the fate and persistence of a fungus like A. flavus are not all seriously taken into consideration before a decision is made.

Thank you,

David M. Wilson
Professor
Department of Plant Pathology
University of Georgia
P.O. Box 749
Tifton, GA 31794

229 369 3368 phone, 229 386 7285 fax
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Size: 10752 bytes.
Type: Unknown

The need for uniform standards1

Comments, identified by docket control number PF-1076, must be received on or before April 24, 2002.

Source -- Wilson, D.M., Mubtanhema, W., and Jurjevic, Z. (2002) Biology and ecology of mycotoxigenic Aspergillus species as related to economic and health concerns. In Mycotoxins in Food. Eds. L.S. Jackson, M.W. Trucksess and J.W. DeVries, Plenum, New York. pp 195-204.

BIOLOGY AND ECOLOGY OF MYCOTOXIGENIC ASPERGILLUS SPECIES AS RELATED TO ECONOMIC AND HEALTH CONCERNS.

David M. Wilson,1 Wellington Mubatanhema,1 and Zeljko Jurjevic2

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ABSTRACT

The fungal genus *Aspergillus* was established in 1729, and includes species that are adapted to a wide range of environmental conditions. Many aspergilli produce mycotoxins in foods that may be toxic, mutagenic or carcinogenic in animals. Most of the *Aspergillus* species are soil fungi or saprophytes but some are capable of causing decay in storage, disease in plants or invasive disease in humans and animals. Major agricultural commodities affected before or after harvest by fungal growth and mycotoxins include corn, peanuts, cottonseed, rice, tree nuts, cereal grains, and fruits. Animal products (meat, milk and eggs) can become contaminated because of diet. *Aspergillus flavus*, *A. parasiticus*, *A. ochraceus*, *A. niger*, *A. fumigatus* and other aspergilli produce mycotoxins of concern. These include the aflatoxins and ochratoxins, as well as cyclopiazonic acid, patulin, sterigmatocystin, gliotoxin, citrinin and other potentially toxic

metabolites.

INTRODUCTION

There is a saying in the real estate industry that prices are governed by location, location, location. All other considerations including marketability and possible use of the property depend on the location and local needs. Mycotoxin contamination of foods and feeds and the associated problems also depend primarily on the production, storage and marketing location. The Aspergillus species that produce mycotoxins are more common in the warmer, subtropical and tropical areas than in the temperate areas of the world. Stringent government regulations for mycotoxins and risk analyses on the other hand are more common in temperate areas than in the warmer areas of the world. Therefore, one must be naive to think that the health and marketplace risk factors considered to be important for the control and management of unavoidable mycotoxin contamination are always science-based. Mycotoxin risk analysis, regulations and management practices to assure health of consumers and markets should be science-based as far as possible, but with the marketing and world trade issues, often deliberations on these factors are as much political as science based. The critical elements needed for mycotoxin management are interdisciplinary in nature.

The toxic secondary metabolites are produced by fungi so there is a critical need to have accurate fungal taxonomy. Fungal metabolites are often produced in low or trace concentrations so there is also a critical requirement for excellence in analytical assays. Mycotoxins occur in many crops and stored seed as well as in processed and formulated products. Therefore, many areas of crop production, mycology, plant pathology, entomology, engineering and chemistry as well as storage and food sciences have to be adequately addressed in relation to the biology and ecology of the mycotoxigenic fungi.

There are many mycotoxins produced by Aspergillus species. The mycotoxigenic aspergilli are usually considered to be saprophytes that can grow in products stored with high moisture content. Colonization of stored products by the aspergilli is primally a function of location and moisture content complicated by insect and rodent activity. Some Aspergillus species produce mycotoxins in meats such as country ham, sausage, cheese or other fermented products; these processes are beyond the expertise of the present authors and will not be addressed. There are only a few mycotoxins that are regularly monitored in the marketplace and we will briefly consider the global and agronomic factors related to aflatoxin, sterigmatocystin, cyclopiazonic acid and ochratoxin A contamination of foods and feeds.

The genus *Aspergillus* was first described and named in 1729 by Pier Antonio Micheli in his monograph "Nova Planetarium Genera" (Micheli, 1729). Micheli named the genus after the holy water sprinkler (aspergillum). The aspergilli are most often soil fungi or saprophytes but several are important because they produce mycotoxins. The aspergilli can also cause decay and deterioration in stored products, and may cause disease in plants, insects, poultry, humans and other mammals. In addition to being disease agents some aspergilli are important aeroallergens. Some of the Aspergillus species and teleomorphs that potentially produce mycotoxins include *A. candidus*, *A. clavatus*, *A. flavus*, *A. fumigatus*, *A. niger*, *A. nomius*, *A. ochraceus*, *A. parasiticus*, *A. restrictus*, *A. tamarii*, *A. terreus*, *A. versicolor*, *Emericellanidulans*, and *Eurotium amstelodami* (Frisvad and Samson, 1991). A partial list of the mycotoxins includes the aflatoxins, citrinin, citreoviridin, cyclopiazonic acid, gliotoxin, ochratoxin, penicillic acid, sterigmatocystin, xanthomegnin and other potentially important metabolites (Frisvad and Samson, 1991).

COMMODITIES AND TISSUES CONTAMINATED BY MYCOTOXINS

Aflatoxin Contamination

The Food and Drug Administration in the United States, The Institute of Public Health in Japan and many other agencies around the world regularly test products in the marketplace for aflatoxins. The following products in the marketplace have been reported to be contaminated with aflatoxins or aflatoxin metabolites: almonds, Brazil nut, filberts, pistachio nut, cashew nut, walnut, pecan, figs, melon seed, pumpkin seed, sesame seed, sunflower seed, lotus seed, coix seed, marzipan, red pepper, white pepper, nutmeg, paprika, mixed spice, rice, corn (maize), corn products, mixed cereals, peanuts, peanut products, crude sugar, soybean meal, beans, buckwheat, chilies, chili powder, cocoa products, cotton, copra, sorghum, millet, snack foods, eggs, milk, cheese, yogurt and meats (Wilson and Abramson, 1992). Human tissues and fluids that have been shown to contain aflatoxin after exposure include urine, human milk, blood, liver, kidney and various other tissues. Aflatoxin and cyclopiazonic acid have been seen to occur together in corn and peanuts (Urano, et al, 1992). These lists are not complete and are in no particular order. The products are not ranked as to the relative risk to consuming animals or people. The large number of products that may contain aflatoxins illustrates the severity of the problem and the low probability that easy and effective solutions will ever be possible. For aflatoxins there is no doubt that some crops are contaminated because they have been invaded and colonized by *A. flavus* and associated species before harvest. Some crops and products

are contaminated in storage and processing so some manufactured products may contain aflatoxins from both preharvest and postharvest accumulation. Most often the manufacturing process will not detoxify the toxins and the products will be marketed and consumed. Humans are also exposed to the aflatoxins and their metabolites by consuming animal products contaminated because the animal ate feed containing aflatoxin.

Ochratoxin Contamination

Literature on contamination of crops and products with ochratoxin A and associated metabolites is not as easily located or as directly associated with a particular fungus as is the case with the aflatoxins. We have relied on the review by Wilson and Abramson (1992) and internet computer searches complemented with current literature to generate the list. Ochratoxin is also likely to occur with other mycotoxins such as citrinin and penicillic acid or patulin. The following products and tissues have been reported to be contaminated with ochratoxin or its metabolites: barley, wheat, coffee, table wine, grape juice, beer, meats, cocoa, baby foods, feed grains, corn, oats, cereals, rye, crackers, raisins, pecans, figs, pig blood, pig kidneys, other animal tissues and human blood. The principal crops affected tend to be those grown in temperate regions. Most likely the penicillia rather than the aspergilli are the major source of ochratoxin A in temperate zones. The aspergilli may be very important in the warmer zones of the world, but this distribution is not well documented, perhaps because no one has looked in these regions, or maybe the aspergilli that produce ochratoxin A are not particularly aggressive in preharvest and storage situations in these climates. There needs to be much more information generated on how and why ochratoxin A contaminates products, other than coffee, that are produced in the warmer and tropical climates.

ANALYTICAL CONSIDERATIONS

There are really two analytical method approaches needed, one for mycotoxin regulation and another for mycotoxin research. These approaches are actually quite different in their nature. The analytical needs for research often require a wide analytical range and those for regulatory purposes necessarily use a narrow concentration range, sometimes near the analytical detection limit. Consequently, methods used for mycotoxin regulation require a high degree of accuracy at extremely low concentrations. There are currently several official AOAC International methods for aflatoxins designed for the 20 ppb (nanogram/gram, ng/g) United States of America standard and a few

methods for the European Union 2 ppb standard (Cunniff, 1995). None of these official methods take into account the tremendous sampling problems and mycotoxin distribution variations that are associated with aflatoxin measurement in large lots. However, there are elaborate sampling plans in many regulations (Coker, 1998). It is quite likely that the European Union regulations require aflatoxin concentrations in products that are far below the farmers' capability to manage mycotoxins when crops are grown between 35EN and 35ES. The European Union regulation for aflatoxin requires the shipper to pay for transporting the product back to the point of origin if the aflatoxin content is too high. The United States regulations take some of the natural variation into account and the United States allows products to be marketed on the basis of use, and in this way minimizes human exposure.

For research purposes, rapid and inexpensive analytical and screening methods for aflatoxins that are accurate between 0 and 40,000 ppb are critically needed. Similar research needs exist for methods for ochratoxin A, cyclopiazonic acid and sterigmatocystin assays. Analytical costs and ease of use are also important factors in the development and implementation of regulatory methods as well as applied research methods. There is a critical need for methods designed for research as well as regulatory applications if we are indeed serious about mycotoxin management worldwide.

FUNGAL CONSIDERATIONS

Aflatoxin and Cyclopiazonic Acid Producing Fungi

The taxonomy of Aspergillus species is not easy but it is relatively straightforward when compared to the taxonomy of Penicillium species. The book by Raper and Fennell (1965) remains the major guide to taxonomy of the Aspergillus genus. Klich and Pitt (1988) have incorporated subsequent taxonomic revisions and new species into a laboratory guide to the common Aspergillus species. The Aspergillus species that produce the aflatoxins are all in the subgenus Circumdati, section Flavi. The species in this section include: *A. flavus*, *A. oryzae*, *A. parasiticus*, *A. nomius*, *A. sojae* and *A. tamarii*. The only fungi that have been unequivocally demonstrated to produce the aflatoxins are *A. flavus*, *A. parasiticus*, and *A. nomius*. The other three species in the Flavi section do not produce aflatoxins. It is interesting that Kurtzman et al (1986) used DNA relatedness to suggest that *A. flavus*, *A. parasiticus*, *A. sojae* and *A. oryzae* should be a single genus. Kurtzman et al (1986) proposed that *A. flavus* be used with the varieties being flavus, parasiticus, sojae and oryzae. Klich and Pitt (1988) did not think this suggested change in nomenclature was warranted.

Dr. Dorothy Fennell prepared an unpublished outline in 1976 for distinguishing *A.flavus* and *A. parasiticus*. She stated in this manuscript that "Cultural and morphological differences between strains identified unequivocally as *A. flavus* by our criteria cannot be correlated with aflatoxin production. Strains that appear identical may produce much or no B. It is almost safe to say they produce no G. In general *A. flavus* produces aflatoxin B1, and B2 when the isolate is aflatoxigenic, many isolates of *A. flavus* produce no aflatoxins in culture." Some aflatoxigenic as well as some non-aflatoxigenic isolates of *A. flavus* also produce cyclopiazonic acid which is independent of the ability to produce aflatoxin (Horn and Dorner, 1999). Wicklow and Shotwell (1983) reported that the sclerotium of some isolates of *A.flavus* may contain aflatoxin B1 and G1 and Cotty and Cardwell (1999) reported that S strain isolates of *A. flavus* from West Africa produced aflatoxin B1 and G1 while no North American S strain isolates produced aflatoxin G1. Almost all aflatoxigenic *A. parasiticus* and *A. nomius* isolates produce the B and G aflatoxins. For these reasons we do not think that the use of aflatoxin production patterns is a stable character that is useful for nomenclature in the section Flavi.

S N Am. no G1

Calvert et al (1978) demonstrated that the B to G ratios in preharvest corn were affected by mixed inoculum of *A. flavus* and *A. parasiticus* and Wilson and King (1995) showed similar results in mixed cultures. Wilson and King (1995) reported that in mixed cultures of *A. flavus* and *A. parasiticus* the production of G1 and G2 by *A. parasiticus* was depressed when there was at least 25% of *A. flavus* in the original conidial mixture. Perhaps *A. flavus* suppresses the production of aflatoxin by *A. parasiticus*.

A. flavus and *A. parasiticus* have both been reported to grow and produce toxins in
preharvest and stored products. Many people do not identify the *A. flavus* group (equivalent to the Aspergillus subgenus Circumdati section Flavi) to the species level, so much of the literature cannot be evaluated as to the importance of the individual species in relation to observed real world contamination. The FDA data referred to in the chapter by Wilson and Abramson (1992) illustrate the variable nature of the B to G ratios that naturally occur in various products.

Cotty (1997) has grouped *A. flavus* into S and L strains based on sclerotial size. In southern United States cotton producing areas, Cotty (1997) found that *A. flavus* and *A.tamarii* incidence differed between geographic areas and that *A. flavus* incidence was correlated with high minimum temperatures and inversely correlated with latitude. Odum et at (1997) looked at the spatial and temporal patterns of the S and L strains in Yuma County, Arizona. The highest incidence of S strain isolates was during cotton boll formation and the highest *A. flavus* propagule density in the soil was in the summer. Horn and Dorner (1999) looked at soil

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populations of Aspergillus species of the section Flavi along a transect from eastern New Mexico through Georgia to eastern Virginia. There was a large population variation in the 166 cultivated fields with high densities of the section Flavi centered from east-central Texas to south-central Georgia. *A. flavus* was the dominant species along most of the transect. The S strain was mostly in the cotton growing regions of east-central Texas and Louisiana. *A. parasiticus* incidence was highest from south-central Alabama to eastern Virginia. *A. nomius* was detected only in Louisiana and Mississippi. Georgia and Alabama had the highest Flavi section soil populations and western Texas had the lowest populations. Horn and Dorner (1999) suggested that the population differences were related to drought and soil temperatures. It would be interesting if there were similar population changes in transects from cultivated soils taken in the United States from the Canadian border to south Florida. Most likely soil populations and the risks of aflatoxin contamination are influenced by weather patterns, soil moisture and soil temperature, with hot dry soils favoring the Aspergillus section Flavi.

Cyclopiazonic Acid Producing Fungi

Cyclopiazonic acid is produced by several Aspergillus and Penicillium species in addition to being produced by *A. flavus*. The fungi that have been reported to produce cyclopiazonic acid include *P. verrucosum*, *P. camembertii*, *P. patulum*, *P. puberulum*, *A. versicolor*, *A. oryzae* and *A. tamarii* (Wilson and Abramson, 1992). There is little information on the importance of cyclopiazonic acid in crops, so further investigation on factors affecting cyclopiazonic acid incidence is warranted.

Sterigmatocystin Producing Fungi

Little is known about sterigmatocystin and the fungi that produce the toxin. Studies in Japan and Canada by Sugimoto et al. (1976) and Abramson et al. Mills (1983) determined the relationship between *A. versicolor* and production of sterigmatocystin in postharvest storage. The other aspergilli that produce sterigmatocystin include *A. rugulosus*, *A. nidulans*, *A. flavus*, *A. parasiticus*, *A. chevalieri*, *A. ruber*, *A. amstelodami*, *A. aurantobrunneus*, *A. quadrilineatus*, *A. sydowii* and *A. ustus*. Sterigmatocystin can also be produced by penicillia including *P. griseofulvum*, *P. commune* and *P. camembertii* (Wilson and Abramson, 1992). Little is known about the potential for sterigmatocystin production by these fungi in nature. Non-aflatoxigenic *A. flavus* and *A. parasiticus* could possibly have the aflatoxin biosynthesis pathway blocked in such a way as to be potentially efficient producers of sterigmatocystin or sterigmatocystin derivatives.

Ochratoxin Producing Fungi

A. ochraceus is likely the most important Aspergillus species involved with ochratoxin A contamination in storage. Possibly this fungus occurs before harvest or during drying and curing which could result in ochratoxin A contamination at harvest in some situations. Ochratoxin A found in cereals in storage is primarily produced by growth of *Penicillium verrucosum* , and perhaps the associated Aspergillus species, *A. ochraceus* and *A. ostianus* (Frisvad, 1995). However, Frisvad (1995) questions whether *A. ostianus* actually produces ochratoxin A sensu stricto. Naturally occurring ochratoxin A has not been linked to Aspergillus species in grain stored in warm climates but has been found in stored coffee beans invaded by *A. ochraceus* (Frisvad, 1995).

A partial list of the Aspergillus and Penicillium species that have been reported to produce ochratoxin A includes: *A. alliaceus, A. carbonarius, A. melleus, A. niger var. niger, A. sulphureus, A. sclerotiorum, A. niger var. awamori, A. ostianus, A. petrakii, P. verrucosum, P. palitans, P. commune, P. purpurascens, P. variable* and *P. chrysogenum*. (Wilson and Abramson, 1992; Hocking, 2001; Abarca et al, 1994; Heenan et al., 1998; Horie, 1995). Most of the Aspergillus species are closely related to *A. ochraceus* and are in the subgenus Circumdati, section Circumdati, with *A. carbonarius, A. niger var. niger* and *A. niger var. awamori* being in the subgenus Circumdati, section Nigri. Apparently the biosynthetic pathway for ochratoxin production is common in several Aspergillus and Penicillium species.

Most likely there are only a few species responsible for ochratoxin A contamination of foods. The Penicillium species that occur and produce ochratoxin A generally occur in temperate zones whereas the Aspergillus species are most likely more important in warmer zones of the world. It is not clear which of the Aspergillus species in addition to *A. ochraceus* may be important. In addition, it is not certain if ochratoxin A contamination is only a storage problem or perhaps a dual field and storage problem. The report of *A. ochraceus* infested coffee berry borer acting as a possible vector of *A. ochraceus* (Vega and Mercadier, 1998) suggests that the possibility of preharvest ochratoxin A contamination of coffee needs to be investigated in the same ways as preharvest aflatoxin was investigated. It is not apparent exactly which of the ochratoxigenic aspergilli produce ochratoxin A in warm subtropical and tropical climates, but *P. verrucosum* and *A. ochraceus* are both likely to be important in temperate climates.

ECOLOGICAL AND PLANT PATHOLOGICAL CONSIDERATIONS

Preharvest, Harvest and Drying Factors

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The aflatoxins, cyclopiazonic acid and possibly ochratoxin A can be produced in the field, during the growing season or in the curing and drying processes prior to storage. Little is known about ochratoxin A contamination in the field. Vega and Mercadier (1998) isolated *A. ochraceus* from adult coffee berry borers isolated from coffee beans in Uganda and Benin. The coffee berry borer is a major insect pest of coffee. Preharvest and postharvest insect vectors of *A. ochraceus* and insect damage may be important in increasing the risk of ochratoxin A contamination. Bucheli, Kanchanomgi and Pittet (2000) stated that sun drying of coffee cherries consistently led to ochratoxin A formation in the pulp and parchment (husks) of the cherries in Thailand. Dried beans contained about 1% of the ochratoxin A found in husks. Maturity of the coffee cherries at harvest affected the susceptibility of the crop to ochratoxin A contamination. Many more studies are needed to understand the factors that affect ochratoxin A contamination in coffee and all other susceptible crops.

The aflatoxins, cyclopiazonic acid and sterigmatocystin can all be produced by *A.flavus* while *A. parasiticus* is not known to produce cyclopiazonic acid. Wilson (1995), Wilson and Abramson (1992), Wilson and Payne (1994), Payne (1998), Dowd (1998), Widstrom (1992) and others have reviewed preharvest mycotoxin contamination in crops and we will only add a few observations to the generally accepted views on contamination. Aflatoxin and most likely cyclopiazonic acid contamination before harvest is common in many crops with an increased probability of occurrence of these mycotoxins in the warmer, sub-tropical and tropical climates compared to the temperate climates of the world.

Climate in the production area is the most important factor influencing the preharvest contamination of corn, peanut, cottonseed and tree nuts with aflatoxin. Dry weather and droughts are very important prerequisites for contamination of corn, cotton and peanut. Thus in Iowa, aflatoxins are occasionally seen in corn before harvested during the summers with late season drought. In Georgia, weather related aflatoxin contamination is chronic, but is most severe in dry years. Irrigation of corn in North Carolina is effective in reducing aflatoxin contamination in corn while in Georgia, irrigation is not always effective in reducing contamination. Insect damage is related to increased aflatoxin content in many crops. However, temperature and moisture effects override the insect effect. The insect effects depend on the time of planting and maturity of corn in Georgia. Late planted corn often has less aflatoxin contamination but more insect damage than early planted corn. Other stress factors such as plant density, fertility and plant disease interact with the environment to increase or decrease the risk of aflatoxin contamination. Widstrom (1992) described the infection and colonization period of corn by *A. flavus* between silking at about 60 days after planting until physiological

maturity at about 120 days. There was increasing damage to the ear by insects from silking to harvest at 135 days after planting. There was a continuous post-infection aflatoxin accumulation from silking to harvest. The optimal temperature for corn production is lower than the optimal temperature for *A. flavus* growth and insect damage. Consequently, there are positive correlations between the average temperature, aflatoxin contamination and insect damage. This is especially evident when temperatures become too high for optimum corn growth. Widstrom (1992) used data from planting date studies in Georgia to illustrate the effects of temperature on aflatoxin contamination at harvest. Ears that are developing and maturing when the temperature is 28 - 32O C are much more susceptible to aflatoxin contamination than ears that develop at lower temperatures when the corn is planted later. The insect damage effects were not as important as the temperature effects in the planting date study. However, planting corn late is not an effective control measure because late planting of corn results in a reduced yield and it is not profitable to grow corn under these conditions. In corn as well as in peanuts and cottonseed, cyclopiazonic acid contamination most likely parallels the incidence of aflatoxin contamination. We do not have any absolutely effective management strategies for aflatoxin control other than growing crops in low risk areas.

Management of aflatoxin contamination of preharvest peanuts was reviewed by Wilson (1995). The most important factors favoring and controlling contamination include location, soil moisture, soil temperature and insect activity. Mites, lesser corn stalk borers in the United States and probably termites in Africa are efficient vectors of the *A. flavus* group. Damage by these insects creates a favorable habitat for growth of the fungi and aflatoxin production. Aflatoxin content of peanuts is most affected by the soil moisture and temperature but aflatoxin contents may also be increased by insect damage. Late season irrigation increases soil moisture and decreases soil temperature and is an effective way to lower aflatoxin content in mature kernels. Management factors other than irrigation, such as plant nutrition, fungicide applications, insecticide applications and harvesting techniques can all have effects on the final quality and aflatoxin content. Aflatoxin contamination of peanut is quite dependent on the climate and the geographic location. The damage and the rate of drying of peanuts after digging until storage can also have major effects on quality including aflatoxin contamination. The probability of successful preharvest control in peanut is highest in irrigated fields because soil moisture and temperature can be affected by irrigation. Sorting the peanuts to remove damage is also a fairly effective way to remove aflatoxin contaminated kernels. The United States marketing system is designed to facilitate aflatoxin management and the system is somewhat effective in years when there is not a severe hot and dry growing season. In years with severe

drought, the buying-point marketing system is not very effective and aflatoxin removal methods have to be carefully implemented by peanut shellers and manufacturers of peanut products.

Aflatoxin contamination in cottonseed is primarily related to the environment. It is mostly associated with desert environments in the United States and elsewhere where the temperature and water stresses on the growing plants are outside the optimum for the plant to develop properly. Scientists at the USDA laboratory in New Orleans have made many advances in understanding the relationships of the cotton plant to the insect and environmental stresses, but the environment overrides all practical control measures. Therefore, detoxification and alternative use research studies are sorely needed to insure that the contaminated cottonseed has a market outlet.

Designing management strategies for tree nuts, especially the Brazil nut, is an even greater challenge than the dilemma faced by cotton producers in Arizona. The Brazil nut tree is a major overstory component of the South American Amazon basin forest region and the Brazil nut is an extractable product of Amazonia. The very large trees grow in the forest, not in plantations, so the production of nuts cannot be managed in any practical manner. The nuts fall to the ground enclosed in cannonball-like structures about the size of a grapefruit during the rainy season. The seeds are arranged in the woody coconut-like fruit similar to the way orange slices are in oranges. The nuts are gathered by hand after the coconut is opened using a machete and then they are carried in bags to collection places in the forest for transport to processing facilities after the rainy season. The nuts are very resistant to decay and insects, but *A. flavus* group species frequently grow on the stored product which results in aflatoxin contamination. There is a tremendous need to develop postharvest strategies for sorting and other aflatoxin control measures in this tropical region. Marketing of the Brazil nut is a good example of the conflict we often see between governmental regulations and global needs for the protection of the environment. The earth's climate benefits from the Amazon forest while local consumers, as well as those in other countries, need to be able to purchase products that are safe. Excluding the Brazil nut from the markets in either the developed or developing countries may have a minimal effect on the aflatoxin risk in the developed and developing countries, but cutting all the Brazil nut trees for timber would have a negative global weather consequence. The biological factors leading to aflatoxin contamination of corn, peanuts, cotton seed and Brazil nut are similar in some respects and very different in others. Designing ways to insure that aflatoxin contamination is not a human health risk is complex. Multi-disciplinary approaches are needed to accomplish the goal of providing safe wholesome food worldwide, not just in the developed countries.

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Storage Factors

Fungal deterioration of foodstuffs in storage is a complex issue depending on the habitat and the storage conditions. The growth of fungi in stored grains and oilseeds has been well described and reviewed many times and the important factors need not be repeated here. Recent reviews include those by Ominski et al (1994), Frisvad, (1995), Lacey and Magan, (1991), Abramson, (1991) and the books edited by Chelkowski, (1991), Sauer, (1992), and Jayas et al. (1995).

The literature on storage is extensive and the basic biological, moisture and structure requirements are readily available elsewhere. There are a few considerations relating to storage that are worth mentioning in relation to the aspergilli. First, the concept of field versus storage fungi as elaborated by Christensen (1974) was based on work done in a temperate climate in Minnesota. The incidence of many of the so-called storage fungi, particularly the aspergilli, that occur in the field increases as crops are produced from the higher to lower latitudes, so location is an important factor. The aspergilli that are present on crops as they enter storage are more common in the warmer and humid climates so the fungal succession in storage is dependent on location and temperature. Therefore, *A. flavus* is a storage fungus in Minnesota and Kansas and a field and storage fungus in warmer climates like Georgia. The climatic factors related to colonization and warm temperatures can result in a rapid accumulation of aflatoxins in the field as well as in storage in the warm humid, subtropic and tropical climates. There is a great need to do field and storage studies from high to low latitudes to define the location and environmental effects on mycotoxin contamination.

Lacey and Magan (1991) critically examined the relationships between the fungi, water content and temperature in cereal grains. Beti et al. (1995) found that maize weevils facilitate the growth of *A. flavus* in stored corn by acting as vectors for inoculum and by increasing the moisture content as well as increasing the surface area susceptible to fungal colonization. Aflatoxin accumulation can be quite profound in corn with weevil activity even in stored corn with initially low populations of *A. flavus*. We have seen that same situation in Georgia, but it is interesting that once the stored corn accumulates high aflatoxin concentrations the active weevil population rapidly decreases. In many parts of the world maize is stored locally by smallholder producers and consumers. Udoh et al. (2000) studied the storage structures in five agroecological zones of Nigeria and related the storage practices to aflatoxin content. Corn stored in polyethylene bags was particularly prone to aflatoxin contamination because of moisture retention as was the corn with insect infestations. Farmers in Nigeria were not eager to accept new methods for storage and there were many storage situations that could be improved to help

maintain quality. The major problems observed usually related to the maize moisture content, insect activity, ear damage and the lack of sorting the maize for quality before storage. There is a critical need for research on effective and acceptable ways to improve smallholder produced maize and other products when they are stored in developing countries in the warmer regions of the world.

There is not enough information about the conditions affecting accumulation of cyclopiazonic acid, sterigmatocystin and ochratoxin A by aspergilli in storage situations worldwide to draw meaningful conclusions that have not already been addressed by authors like Abramson (1991) and Mababe and Tsurta (1991)

BIOLOGICAL CONTROL STRATEGIES

Biological control of mycotoxigenic fungi by competition, replacement or exclusion of toxin producing fungi has a great appeal. However, is this a practical approach that farmers can safely and profitably implement? The use of competitive microorganisms and mycoparasites to control the growth of fungi in field and storage situations has not often proved practical.

Wilson et al. (1986) used several *A. flavus* and *A. parasiticus* mutants to study infection and aflatoxin accumulation in preharvest corn. One white *A. flavus* mutant did not produce any of the aflatoxins in culture and was somewhat effective in reducing aflatoxin contamination in wound inoculated ears when compared to the untreated check. However, the aflatoxin content rapidly increased over all other treatments in ears inoculated with the non-toxic mutant 20 days post-silk and then infested at 55 days post-silk with maize weevils exposed to a wild type *A. flavus*. Corn plots have been regularly inoculated for many years in Georgia and the aflatoxin content at harvest can easily be affected by the toxin producing ability of the *A. flavus* or *A. parasiticus* used as inoculum. Thus, inoculation with low aflatoxin producers may lower aflatoxin content in certain situations.

Unfortunately nature does not always cooperate and the environmental effects on the corn plant and associated microflora cannot be predicted for all situations. Most often in years that favor preharvest aflatoxin accumulation the *A. flavus* that is the most aggressive in colonizing the ears is the one that has the major effect. If the last isolate to invade is a weak aflatoxin producer, then little aflatoxin may be found. However, if the final invader is a proficient producer then high concentrations of aflatoxin may be seen. Biological control is not particularly needed in years with little risk of preharvest contamination but biological control needs to be extremely effective in high risk years. We

have never been able to obtain consistent results in our inoculation trials using aflatoxin producing isolates in preharvest corn and peanut trials. Therefore, it may be unlikely that field applied non-toxic isolates will consistently reduce contamination, particularly in the years where there is a very high risk of contamination.

Will et al. (1994) evaluated field inoculation techniques for screening peanut genotypes for resistance to aflatoxin contamination. The primary goal was to decrease the number of plots that did not accumulate aflatoxin in the peanuts. Application of a mixture of aflatoxigenic *A. flavus* and *A. parasiticus* inoculum in Georgia did not significantly affect the aflatoxin content of the harvested peanuts but it usually decreased the number of plots that had little aflatoxin in the harvested peanuts. The use of the *A. flavus/A. parasiticus* infested corn matrix at planting did not affect soil populations of the *A. flavus* group at harvest but when the matrix was applied about 60 days after planting, the soil populations of the A. flavus group were increased.

Dorner et al. (1992) used a non-aflatoxigenic *A. parasiticus* isolate to inoculate soil in peanut plots in 1987 for studies carried out in 1987, 1988 and 1989. They reported that the biocompetitive agent was not found in untreated soil but that soil populations of this fungus at harvest were dependent on the initial inoculum level. The fungus persisted in the soil from 1987 to 1988 and the soil populations of the introduced fungus increased from the time of planting until harvest. The 1987 peanuts contained from 4 to 222 ppb of aflatoxin in the edible categories from the treated plots with various drought stress periods. Dorner et al. (1992) felt that aflatoxin concentrations in the edible peanut categories were reduced from 96 to 1 ppb in 1998 and from 241 ppb to 17-40 ppb in 1989 using the biocompetitive approach, but their experiments were not designed for statistical analysis so they could not analyze the data using statistics. Unfortunately, there was also from 577-11,783 ppb of aflatoxin in the peanuts in the damaged category in 1987, 3,908 ppb in the damaged category in 1988 and from 6,700 to 28,500 ppb in the damaged category in 1989. The *A. parasiticus* isolate they used produced O-methylsterigmatocystin and they were able to measure this compound in the edible and damaged categories. The edible categories contained 172 ppb O-methylsterigmatocystin in 1988 while the damage category contained over 13,000 ppb of O-methylsteigmatocystin.

Based on the work published by Dorner et al. (1992), it appears that unless more effective non-toxigenic isolates have been identified this approach will not result in a Georgia peanut crop that will meet the United States 20 ppb guideline as well as the 2 ppb European guideline in drought years. If this is the case then there will be little economic incentive for peanut growers to use the technique. There are other non-aflatoxigenic *A. flavus* and *A. parasiticus* isolates that could be used in peanut or other crops

for biological control. All potentially useful *A. flavus* isolates need to be tested for their ability to produce cyclopiazonic acid, sterigmatocystin and its derivatives as well the other toxic intermediates in the aflatoxin biosynthetic pathway. Toxicity and disease tests in insects, mammals and birds as well an assessment of potential human disease will also need to be done. The allergic properties of the fungus to humans should be an important issue in the risk considerations.

Cotty (1990) has spent many years developing biological control strategies for aflatoxin contamination reduction in cottonseed in Arizona. He has been able to show a reduction of aflatoxin B1 contamination from 66,240 ppb to 650 ppb using his best non-aflatoxigenic *A.flavus* isolate, strain 36, to inoculate bolls 30 minutes after inoculation with a toxin producing strain. He reported that strain 36 could be used to drastically reduce aflatoxin contamination in cottonseed when it was used to artificially inoculate bolls. Cotty and Bayman (1993) reported that co-inoculation with the non-toxic strain 36 and the toxic strain 13 resulted in a reduction of the aflatoxin content by 82-100% in three tests. The numeric comparisons in ppb of aflatoxin B1 from the tests are in test one - 76,000 ppb reduced to 13,680 ppb, in test two - 176,000 ppb reduced to not detectable and in test three - 444,000 ppb reduced to 4,400 ppb. Apparently Cotty's biological control approach has been somewhat more effective in the field and he has been able to obtain an experimental use permit from the EPA for use in Arizona.

A. flavus usually produces B1 and B2. It is possible that the TLC method used by Cotty (1990) used did not separate the compounds completely because thin layer plates or development solvents do not always separate the aflatoxins. It is also possible that Cotty preferred to report only B1 results. However, it is very unclear why there was a change in the way the results were reported from ppb as in Cotty (1989) to ppm in later publications by Cotty (1990) and Cotty and Bayman (1993). If the results are not read carefully the reduction from 76 to 13.7 micrograms/gram of cottonseed (ppm) in test one can easily be misinterpreted by thinking this is a reduction from 76 to 13.7 nanograms/gram of cottonseed (ppb). Aflatoxin concentrations of 76 and 13.7 ppm are both acutely toxic to animals while 76 and 13.7 ppb are below the United States FDA Action Levels for cottonseed to be used for specific animal feeds. The threshold for aflatoxin concentrations in cottonseed to be used for immature and dairy animals is 20 ppb while there is a maximum of 400 ppb allowed for cottonseed to be used for several other animal feeds.

The major pitfall in the widespread application of *A. flavus* in the environment may be unrelated to aflatoxin production. The potential human, animal, bird and insect disease risks from *A. flavus* have to be carefully examined. Furthermore, the possibility of increasing the incidence of human allergy problems related to *A. flavus* in the areas where

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the *A. flavus* is applied has to be determined. Certainly this is a worthwhile research approach. But we must be careful that in our research efforts to alleviate one marketing problem associated with aflatoxins or other mycotoxin contamination that we do not create other severe long term health or environmental problems. There are also serious food adulteration questions that will have to be addressed. When a farmer intentionally applies a known human allergen that is also a potential human pathogen, such as a non-aflatoxigenic *A. flavus* to his crop, does he adulterate his product as defined by the federal pure food laws and make it unmarketable in the United States? Certainly if a farmer is judged to have adulterated his crop he will lose the market and make no profit.

There are currently available commercial detoxification methods for aflatoxin contamination of cottonseed that can be used. There should also be research on alternative uses of cottonseed that will not be as affected by the excessive aflatoxin content associated with particular desert locations.

MARKETING, REGULATION AND RISK MANAGEMENT FACTORS

The farmer looks at mycotoxin management in his crops and products in a much different way than the buyers, regulatory agencies, processors and consumers of the products. From a human health standpoint there has to be a minimal risk to the consumer of foods and feeds. However, for mycotoxins like the aflatoxins and ochratoxin there is no way to eliminate them from all products and we are forced into developing management strategies. The strategies have to be tailored for the mycotoxin of concern, the product, the marketplace and the geographical location of the consuming public. If the developed countries do not maintain markets and uses for many of the products then we just shift the health and economic risks to the developing countries. Therefore, there is a need for suitable sorting, detoxification and utilization method development to lower the risk worldwide.

First and foremost, there is a need for worldwide harmonization of mycotoxin regulations. Currently there is one set of guidelines for the United States, another for the European Union, and many other guidelines in developed and developing countries. The current situation creates chaos in the international marketplace. Even in the United States the FDA guidelines for shelled raw peanuts in the market are higher than the peanut industry requires in purchase contracts. Given the fact that the sampling error in peanut lots always contributes the greatest variation in the analysis, one must ask is there really a difference in the risk to human health in raw shelled peanut lots containing 25 ppb, 20 ppb, 15 ppb, 10 ppb, 5 ppb or even 2 ppb total aflatoxins? It is doubtful that we can

reliably measure aflatoxin concentrations in peanut lots with great enough accuracy to answer this question (Whitaker and Park, 1994). The second question that is also logical is why the European Union regulations are 2 ppb in finished products? Is this regulation based on a realistic risk analysis or is this a way to manage the marketplace and protect locally produced products? One difference between the two approaches may be that the United States produces products that are at risk for aflatoxin contamination and the European Union is at a very low risk for aflatoxin contamination in the products produced in the member countries. The different regulations make sense from the standpoint of the risk related to domestically produced products. However, both the United States and European Union regulations may exclude many products such as Brazil nuts, pistachio nuts, peanuts, corn, figs and other commodities that may be very important to the welfare of the developing countries' economies as well as to worldwide community health and global ecology. We do not currently have easy solutions that will eliminate the risk of mycotoxins in our food. We need to have logical and fair approaches that are effective in managing the actual health risks rather than perceived risks. At the sixth ICRISAT regional groundnut meeting for western and central Africa held in Mali in 1998, Mr. P. Dimanche from CIRAD-CA in France talked about recent trends in European aflatoxin regulations and said "The regulations for tolerance levels have been laid down in response to concerns for human health. These regulations have continued to become increasingly stringent, as the tolerance level is directly linked to the development of increasingly refined methods of analysis." (Dimanche, 2000). The danger may be that the regulatory community may be willing to set the maximum limits in international commerce based on current analytical capabilities, rather than on realistic health factors.

There can be no argument that there is no defined "no effect level" for aflatoxin but there are multiple ideas about what the realistic allowable risk should be. It seems that a large part of the regulatory approach often depends on latitude and the probability of contamination of locally produced products. It is not possible to remove *A. flavus* or other fungi from the environment so we must develop mechanisms to minimize aflatoxin exposure while understanding that mankind cannot totally eliminate the health risks. There are similar risk issues about ochratoxin and there will be continuing risk considerations about other mycotoxins. Many of the developed countries have been slow in establishing guidelines on locally produced products when a particular mycotoxin occurs in the marketplace. The European Union has published proposed tolerable daily intakes for ochratoxin A while also considering local and import regulations for commodities such as coffee. This approach seems logical and makes much more sense in the long run than basing mycotoxin regulation on analytical capabilities.

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CONCLUSIONS

Mycotoxin contamination of foods by the aspergilli is a very complicated issue. The biological factors allowing the growth of the Aspergillus species that produce mycotoxins are dependent on the fungus, the product and the location. Aspergillus species tend to be more prevalent in the warm, sub-tropical and tropical climates than in temperate climates. We cannot eliminate mycotoxin contamination from our foodstuffs, but we should strive to minimize their adverse effects by using the best practices possible. Mycotoxin contamination is a global issue and perhaps the developed countries tend to overemphasize the risks while the developing countries may tend to underestimate the risks. Therefore we need to work together to improve food security and food safety worldwide in order to foster international cooperation and develop or maintain markets and protect human health.

Mankind cannot manage all aspects of the food supply and there is a point where we have to admit some risks are presently unavoidable. The August 2000 issue of the National Geographic Magazine article "Fungi" had a sentence that seems to be very appropriate: "Intentional or not humans and fungi are partners from cradle to grave." (Murawski, 2000). The challenge posed is simply how can we devise ways to utilize minimally contaminated products in the marketplace even if it means that effective resorting, processing and detoxification treatments may be necessary?

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DATES: Comments, identified by docket control number PF-1076, must be received on or before April 24, 2002.

Abstract presented at the Aflatoxin elimination workshop, Phoenix, AZ, 2001

The need for uniform standards, methods and reporting of data from biocontrol studies using atoxigenic Aspergillus flavus and A. parasiticus.

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Abstract

This is an open request for the industry and scientific community to develop uniform standards for reporting results concerning aflatoxin contamination and fungal incidence in biocontrol studies. The results need to be presented in ppb and the fungal field studies need to be logical and based on the probable fate and persistence of the biocontrol fungi. The studies need to take into account the agricultural, processing and consumer environments as well as regulations and human health concerns.

Rationale for developing uniform standards, methods and data reporting

- Aflatoxin concerns - Many times results from biocontrol studies are not reported in ppb but are presented in ppm or in percent aflatoxin reduction so there is not a uniform

standard for comparison.

- Target concerns - The FDA has several aflatoxin guidelines so different crops and uses may have different aflatoxin goals.
- Fungal concerns - The fate and persistence of applied fungi need to be monitored in the field, in marketing , in manufacturing and through consumer utilization.

Specific concerns about toxin and fungal reporting.

- Cottonseed - Report results in ppb and define if the target is 400 or 20 ppb.
- Corn - Report results in ppb and specify use requirements.
- Peanut - Report results in ppb and specify risk and grade category - eg. sound, mature, immature and damage category. Evaluate all biocontrol isolates for plant disease potential in seed and in the field.
- Fungal studies - Monitor populations at least weekly in the air, in the soil, on the plants and movement outside of the field.
- Make sure that the risk assessments on plants, insects, mammals and humans takes into acccount that the fungi in this group are efficient saprophytes and poor invasive pathogens. - This means that risk and pathogenicity studies will rarely be meaningful and fruitful unless the organisms being tested are under stress. For example honey bees might be susceptible when they have underlying stress factors but be resistant when the hive is healthy. For plants A. flavus is rarely a pathogen unless there are suitable environmental or biological stresses so risk and pathogenicity studies need to take this into account. Mammals are apparently normally resistant to infection unless there are underlying impaired immunity factors or treatment with such things as cortiosteroids. Thus, studies on the risk factors need to be carefully constructed taking into account the nature of the fungus as a potential pathogen of humans. Also, the allergenic properties of the fungus must be seriously taken into account.

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Recommendations

- Aflatoxin assessment - Use appropriate methods for measurement and report data in ppb (ng/g).
- Crop assessment - Specify the intended use of the crop. EU requirements and US requirements are different for foods and feeds so the goal should be stated.
- Fungal assessment - Monitor fungal populations in the air, soil and on the plant through harvest. Monitor the product from the field to the consumer. Design and conduct proper risk assessments for the fungus that are based on published information on the conditions favoring invasive disease or allergy responses.

Conclusion

- Aflatoxin control is a serious challenge for United States farmers. It is a marketing as well as a public health issue and there are no easy solutions. However, it is in no one's best interest for the agricultural research community to use different standards for evaluating the different strategies for aflatoxin management in farm products. We should not use one set of standards for marketing and a different set of standards for biocontrol research.

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Part II

Department of the Interior

Fish and Wildlife Service

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50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Final Determinations of Critical Habitat for Wintering Piping Plovers; Final Rule

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AG13

Endangered and Threatened Wildlife and Plants; Final Determination of Critical Habitat for Wintering Piping Plovers

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the Fish and Wildlife Service (Service), designate 137 areas along the coasts of North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas as critical habitat for the wintering population of the piping plover (Charadrius melodus). This includes approximately 2,891.7 kilometers (km) (1,798.3 miles (mi)) of mapped shoreline and approximately 66,881 hectares (ha) (165,211 acres (ac)) of mapped area along the Gulf and Atlantic coasts and along margins of interior bays, inlets, and lagoons.

The population of piping plovers that breeds in the Great Lakes States is listed as endangered, while all other piping plovers are threatened species under the Endangered Species Act of 1973, as amended (Act). All piping plovers are considered threatened species under the Act when on their wintering grounds. Critical habitat identifies specific areas that are essential to the conservation of a listed species, and that may require special management considerations or protection. The primary constituent elements for the piping plover wintering habitat are those habitat components that are essential for the primary biological needs of foraging, sheltering, and roosting, and only those areas containing these primary constituent elements within the designated boundaries are considered critical habitat. The primary constituent elements are found in coastal areas that support intertidal beaches and flats (between annual low tide and annual high tide) and associated dune systems and flats above annual high tide. Section 7 of the Act requires Federal agencies to ensure that actions they authorize, fund, or carry out are not likely to adversely modify designated critical habitat. As required by section 4 of the Act, we considered economic and other relevant impacts prior to making a final decision on what areas to designate as critical habitat.

Texas (Maps were digitized using 1995 and 1996 DOQQs and National Oceanic and Atmospheric Administration's (NOAA) Medium Resolution Digital Vector Shoreline)

Unit TX–1: South Bay and Boca Chica, 2,920 ha (7,217 ac) in Cameron County

The boundaries of the unit are: starting at the Loma Ochoa, following the Brownsville Ship Channel to the northeast out into the Gulf of Mexico to MLLW, then south along a line describing MLLW to the mouth of the Rio Grande, proceeding up the Rio Grande to Loma de Las Vacas, then from that point along a straight line north to Loma Ochoa. The unit does not include densely vegetated habitat within those boundaries. It includes wind tidal flats that are infrequently inundated by seasonal winds, and includes the tidal flats area known as South Bay. Beeches within the unit reach from the mouth of the Rio Grande northward to Brazos Santiago Pass, south of South Padre Island. The southern and western boundaries follow the change in habitat from wind tidal flat, preferred by the piping plover, to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur and include areas used for roosting by the piping plover. Portions of this unit are owned and managed by the Lower Rio Grande Valley National Wildlife Refuge, the South Bay Coastal Preserve, Boca Chica State Park, and private citizens.

Unit TX–2: Queen Isabella Causeway, 2 ha (6 ac) in Cameron County

The area extends along the Laguna Madre west of the city of South Padre Island. The southern boundary is the Queen Isabella State Fishing Pier, and the northern boundary is at the shoreline due west of the end of Sunny Isles Street. The Queen Isabella causeway bisects this shore but is not included within critical habitat. The eastern boundary is where developed areas and/or dense vegetation begins, and the western boundary is MLLW. This unit contains lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–3: Padre Island, 10,924 ha (26,983 ac) in Cameron, Willacy, Kenedy, and Kleberg Counties

This unit consists of four subunits:

(1) The southern boundary of this subunit is at Andy Bowie County Park in South Padre Island, and the northern boundary is the south boundary of PAIS. The eastern boundary is MLLW in the Gulf of Mexico, and the western boundary is MLLW in the Laguna Madre. Areas of dense vegetation are not included in critical habitat. This subunit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

(2) The boundaries of this subunit extend from Rincon de la Soledad to the southeast point of Mesquite Rincon, continue from that point west to the Laguna Madre shoreline at its intersection with the King Ranch boundary, and from that point to Rincon de la Soledad. This subunit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

(3) This subunit is within the Laguna Madre and extends from the western boundary of PAIS to the Gulf Intercoastal Waterway. Its northern boundary is a line extending westward from the northwest corner of PAIS, and its southern boundary is a line extending westward from the southern boundary of PAIS. This subunit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

(4) This subunit extends along the gulf shore of Padre Island from the northern boundary of PIAS at the shore, north to the Nueces-Kleberg county line. The inland boundary is where dense vegetation begins, and the seaward boundary is MLLW. This subunit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Portions of this unit are owned and managed by TGLO, and private citizens with a significant portion being owned and managed by The Nature Conservancy on South Padre Island.

Unit TX–4: Lower Laguna Madre Mainland, 4,980 ha (12,307 ac) in Cameron and Willacy Counties

The southern boundary is an east-west line at the northern tip of Barclay Island, and the southern boundary is an east-west line 0.9 km (0.5 mi) south of the boundary of the City of Port Mansfield; the western boundary is the line where dense vegetation begins, and the eastern boundary is the Gulf Intercoastal Waterway. The unit includes bayside flats that are exposed during low tide regimes and wind tidal flats that are infrequently inundated by seasonal winds. Portions of this unit are within the Laguna Atascosa National Wildlife Refuge, are TGLO-owned, or are privately owned. Beaches and interior wetlands may or may not be used each year because of varying water levels, storm events, or changes in beach characteristics and tidal regime. Water stages vary in this area with meteorological conditions. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur and include upland areas used for roosting by the piping plover.

Unit TX–5: Upper Laguna Madre, 436 ha (1,076 ac) in Kleberg County

The southern boundary is the northern boundary of PAIS, and the northern boundary is the Kleberg/Nueces County line. The eastern boundary is the line where dense vegetation begins, and the western boundary is MLLW. This unit includes a series of small flats along the bayside of Padre Island in the Upper Laguna Madre. It includes wind tidal flats and sparsely-vegtated upland areas used for roosting by the piping plover. These boundaries receive heavy use by large numbers of shorebirds, including piping plovers. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur, and include upland areas used for roosting by the piping plover.

Unit TX–6: Mollie Beattie Coastal Habitat, 241 ha (596 ac) in Nueces County

This unit will be described as two subunits:

(1) Subunit is bounded on the north by Beach Access Road 3, on the east by the inland boundary of critical habitat Unit TX–7, on the south by Zahn road, and on the west by Zahn Road.

(2) The subunit is bounded on the north by Corpus Christi Pass, on the east by US 361, on the south by the north side of Packery Channel, and on the west by the Gulf Intercoastal Watersay.

Some of the uplands are privately owned and the remaining are owned and managed by the TGLO. This unit includes two hurricane washover passes known as Newport and Corpus Christi Passes, and wind tidal flats that are infrequently inundated by seasonal winds. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur and include upland areas used for roosting by the piping plover.

Unit TX–7: Newport Pass/Corpus Christi Pass Beach, 42 ha (104 ac) in Nueces County

This unit is along a stretch of Gulf beach 8.5 km (5.3 mi) long. It is

bounded on the north by Fish Pass, on the east by MLLW, on the south by St. Bartholomew Avenue, and on the west by a line marking the beginning of dense vegetation. Portions of the unit are managed by the Texas Parks and Wildlife Department as part of Mustang Island State Park. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–8: Mustang Island Beach. 97 ha (239 ac) in Nueces County

This is a stretch of Gulf beach extending from Fish Pass to the Horace Caldwell Pier on Holiday Beach within the City of Port Aransas, TX. The landward boundary is beginning of dense vegetation, and the gulf-ward boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–9: Fish Pass Lagoons. 130 ha (323 ac) in Nueces County

This unit encompasses flats facing Corpus Christi Bay that extend 1.0 km (0.6 mi) on either side of Fish Pass. The inland boundary is the line indicating beginning of dense vegetation, and the bayside boundary is MLLW. It includes interior lagoons and wind tidal flats that are infrequently inundated by seasonal winds. This unit includes upland areas used for roosting by the piping plover.

Unit TX–10: Shamrock Island and Adjacent Mustang Island Flats. 87 ha (216 ac) in Nueces County

This unit encompasses Shamrock Island, an unnamed small sand flat to the north of Wilson's Cut, and a lagoon complex that extends 3.5 km (2.2 mi) to the southwest of Wilson's Cut. Critical habitat includes land to the line marking the beginning of dense vegetation down to MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–11: Blind Oso. 2 ha (5 ac) in Nueces County

This unit is the flats of the Blind Oso, part of Oso Bay, from Hans and Pat Suter Wildlife Refuge (owned and managed by the City of Corpus Christi) northeast to Corpus Christi Bay and then southeast along the edge of Texas A&M University—Corpus Christi. The landward boundaries extend to where densely vegetated habitat, not used by the piping plover, begins, and extends out from the landward boundaries to MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–12: Adjacent to Naval Air Station-Corpus Christi. 2 ha (6 ac) in Nueces County

This unit is along the shore of Oso Bay on flats bordered by Naval Air Station-Corpus Christi and Texas Spur 3 to a point 2.5 km (1.5 mi) south of the bridge between Ward Island and the Naval Air Station. The landward boundary is the line where dense vegetation begins, and the boundary in the Bay is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–13: Sunset Lake. 176 ha (435 ac) in San Patricio County

This unit is triangle shaped, with State Highway 181 as the northwest boundary, and the limits of the City of Portland as the northeast boundary. The shore on Corpus Christi Bay is the third side of the triangle, with the actual boundary being MLLW off this shore. This unit is a large basin with a series of tidal ponds, sand spits and wind tidal flats. This unit is owned and managed by the City of Portland within a system of city parks. Some of the described area falls within the jurisdiction of the TGLO. It includes two city park units referred to as Indian Point and Sunset Lake. Much of the unit is a recent acquisition by the city, and management considerations for the park include the area's importance as a site for wintering and resident shorebirds. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–14: East Flats. 194 ha (481 ac) in Nueces County

This unit is bordered on the north by dredge placement areas bordering the Corpus Christi Ship Channel, on the west by MLLW in Corpus Christi Bay, on the east by the limits of the City of Port Aransas, and on the south by an east-west line at the sourthern-most point of Pelone Island. It is also bisected by a navigation channel, which is not included in the critical habitat. A portion of this unit at the west end falls within State-owned (TGLO) intertidal lands. The remainder of the unit is privately owned. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur, including upland areas used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–15: North Pass. 447 ha (1,106 ac) in Aransas County

The unit is bounded on north by North Pass, on the northwest by the line indicating MLLW, on the southwest by the northeast side of Lydia Ann Island, on the south by a line running due east from the northeast side of Lydia Ann Island, and on the southeast by the landward boundary of Unit. This unit is a remnant of a hurricane washover on the privately owned San Jose Island. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur, including upland areas used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–16: San Jose Beach. 187 ha (463 ac) in Aransas County

This unit occupies a 33 km (20 mi) stretch of beach from the North Jetty of Aransas Pass at the south, to the confluence of Vinson Slough and Cedar Bayou at the north end of San Jose Island. The inland boundary is the line indicating the beginning of densely vegetated habitat, and the gulf-ward boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–17: Allyn's Bight. 5 ha (14 ac) in Aransas County

This unit includes shoreline of San Jose Island on Aransas Bay from Allyn's Bight to Blind Pass, the channel between San Jose Island and Mud Island. The inland boundary is where the line of dense vegetation begins, and the bay-ward boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–18: Cedar Bayou/Vinson Slough. 3,051 ha (7,539 ac) in Aransas County

Beginning at the confluence of Vinson Slough and Cedar Bayou, this unit's boundary follows the shore of Spalding Cove to Long Reef, then continues along a line extending (2.5 mi) southwest of Long Reef to the shore of San Jose Island, then along the shore of the island to the landward boundary of Unit TX–16. The unit boundaries extend landward to the line indicating the beginning of dense vegetation. This unit is a remnant of a hurricane washover area, and includes the highly dynamic area of Cedar Bayou, the pass that separates San Jose Island and Matagorda Island. This area includes a small

section of Matagorda Island National Wildlife Refuge with much of the remaining areas occurring on the privately owned island of San Jose. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur and include upland areas used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–19: Matagorda Island Beach. 395 ha (976 ac) in Calhoun County

This stretch of beach along the Gulf of Mexico on Matagorda Island extends a distance of 60 km (36 mi) from Cedar Bayou on the southwest (where it abuts TX–18), to Pass Cavallo on the northeast. The inland boundary is the line indicating the beginning of dense vegetation, and the gulf-ward boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds. The unit falls entirely within the boundary of the Matagorda Island National Wildlife Refuge.

Unit TX–20: Ayers Point. 397 ha (982 ac) in Calhoun County

This unit is an unnamed lake on Matagorda Island between Shell Reef Bayou and Big Brundrett Lake, with San Antonio Bay to the north. The unit boundary extends landward from the lake to the line where dense vegetation begins and where the constituent elements no longer occur and includes upland areas used for roosting by the piping plover. This unit includes marsh and flats at Ayers Point on Matagorda Island National Wildlife Refuge. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–21: Panther Point to Pringle Lake. 863 ha (2,133 ac) in Calhoun County

This unit represents a narrow band of bayside habitats on Matagorda Island from Panther Point to the northeast and of Pringle Lake. The landward boundary is the line indicating where dense vegetation begins, and the bayward boundary is MLLW. The unit is entirely within Matagorda Island National Wildlife Refuge. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–22: Decros Point. 450 ha (1,114 ac) at the Matagorda/Calhoun County Line

This unit includes about 7.0 km (4.3 mi) of beach habitat around the island at the western tip of Matagorda Peninsula between the natural opening to Matagorda Bay and the Matagorda Ship Channel. The upland boundary is the line where dense vegetation begins, and the seaward boundary is MLLW. The adjacent upland is privately owned. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–23: West Matagorda Peninsula Beach. 311 ha (769 ac) of Shoreline in Matagorda County

This unit extends 40 km (24 mi) along the Gulf of Mexico from the jetties at the Matagorda Ship Channel to the old Colorado River channel. The inland boundary is the line indicating where dense vegetation begins, and the gulfside boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–24: West Matagorda Bay/ Western Peninsula Flats. 756 ha (1,868 ac) in Matagorda County

This unit extends along the bayside of Matagorda Peninsula from 7.5 southwest of Greens Bayou to 2.5 km (1.6 mi) northwest of Greens Bayou. The landward boundary is the line indicating the beginning of dense vegetation, and the bayside boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–25: West Matagorda Bay/ Eastern Peninsula Flats. 232 ha (575 ac) in Matagorda County

This unit follows the bayside of Matagorda Peninsula from Maverick Slough southwest for 5 km (3 mi). The unit begins at Maverick Slough to the northeast and extends 5 km (3 mi) to the southwest, enclosing a series of flats along Matagorda Bay. The upland areas extend to where densely vegetated habitat, not used by the piping plover, begins and where the constituent elements no longer occur and include upland areas used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–26: Colorado River Diversion Delta. 5 ha (13 ac) in Matagorda County

This unit follows the shore of the extreme eastern northaast corner of West Matagorda Bay from Culver Cut to Dog Island Reef. The southeastern tidally emergent portion of Dog Island Reef is included within the unit. The landward boundary is the line indicating the beginning of dense vegetation, and the bayside boundary is MLLW. The upland areas includes upland areas used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–27: East Matagorda Bay/ Matagorda Peninsula Beach West. 295 (728 ac) of shoreline in Matagorda County

This unit extends along Gulf beach on the Matagorda Peninsula from the mouth of the Colorado River northeast along the peninsula 23 km (14 mi) to a point on the beach opposite Eidelbach Flats. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–28: East Matagorda Bay/ Matagorda Peninsula Beach East. 129 ha (321 ac) in Matagorda County

This unit extends along the Gulf beach on the northeast end of Matagorda Peninsula from a point 0.8 km (0.5 mi) southwest of FM 457 southwest 10 km (6 mi.) to the southwest side of Brown Cedar Cut. This unit abuts with Unit TX–29 to the north. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–29: Brown Cedar Cut. 119 ha (294 ac) in Matagorda County

This unit extends 2 km (1.2 mi.) both southwest and northeast of the main channel of Brown Cedar Cut along the bayside of Matagorda Peninsula in East Matagorda Bay, and abuts unit TX–28 to the southeast. The landward boundary is the line indicating the beginning of dense vegetation, and the bayside boundary is MLLW. The eastern boundary of TX–29 follows the change in habitat from mud flats preferred by the piping plover, to slightly vegetated dune system adjacent to TX–28. This unit includes upland areas used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–30: Northeast Corner East Matagorda Bay. 120 ha (297 ac) in Matagorda County

This unit is bounded on the north by the Gulf Intercoastal Waterway, on the east by the northeast limit of Matagorda bay up the line where dense vegetation begins, on the south by the boundary of Unit TX–28, and on the west by MLLW. It is a system of flats associated with tidal channels. This unit includes upland areas used for roosting by the piping plover and lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–31: San Bernard NWR Beach. 166 ha (410 ac) in Matagorda and Brazoria Counties

This is a unit composed of Gulf beach, 8.0 km (5.0 mi), and extends from the mouth of the San Bernard River to a point along the beach 14.0 km (8.7 mi) to the southwest. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–32: Gulf Beach Between Brazos and San Bernard Rivers. 108 ha (269 ac) of shoreline in Brazoria County

This unit is a segment of Gulf beach between the Brazos River and the San Bernard River. This unit borders an area known as Wolf Island. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–33: Bryan Beach and Adjacent Beach. 157 ha (388 ac) in Brazoria County

The boundaries enclose a length of Gulf beach between the mouth of the Brazos River and FM 1495. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. A portion of this area is owned and managed by the Texas Parks and Wildlife Department. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–34: San Luis Pass. 110 ha (272 ac) near the Brazoria/Galveston County line

This unit extends along the Gulf side of Galveston Island from San Luis Pass to the site of the former town of Red Fish Cove (USGS 1:24,000 map, San Luis Pass, Texas; 1963, photorevision 1974). The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. Approximately 57 percent of the unit includes flats in the floodtide delta that are State-owned and managed by the TGLO. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–35: Big Reef. 47 ha (117 ac) in Galveston County

This unit consists of beach and sand flats on the north, west, and east shore of Big Reef, down to MLLW. South jetty is not included. The area is currently managed by the City of Galveston. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–36: Bolivar Flats. 160 ha (395 ac) in Galveston County

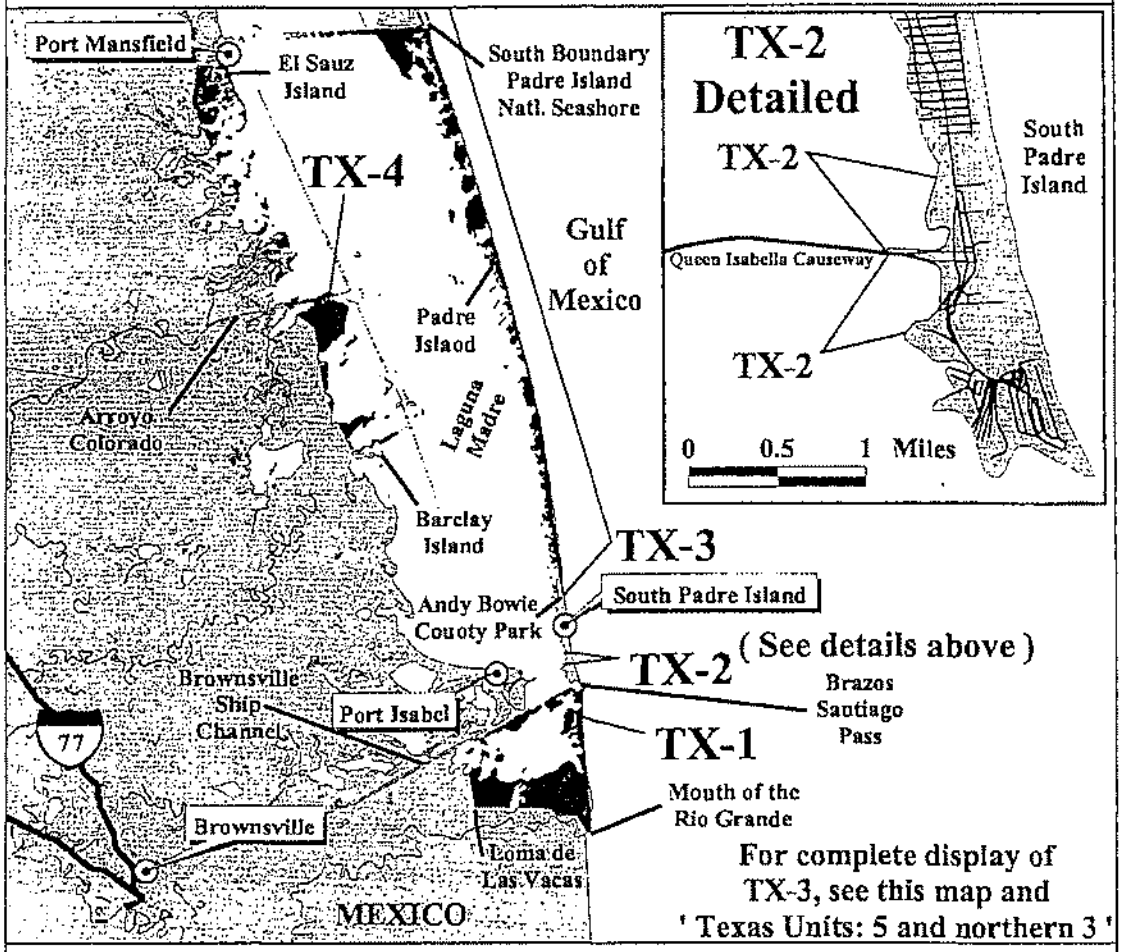
This unit extends from the jetties on the southwest end of the Bolivar Peninsula to a point on the Gulf beach 1 km (0.6 mi) north of Beacon Bayou. It includes 5.0 km (3 mi) of Gulf shoreline. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is MLLW. The area is leased from TGLO by Houston Audubon Society and managed for its important avian resources. The upland areas are used for roosting by the piping plover. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

Unit TX–37: Rollover Pass. 6 ha (16 ac) in Galveston County

This unit consists of Rollover Bay on the bayside of Bolivar Peninsula. The landward boundary is the line indicating the beginning of dense vegetation, and the bayside boundary is MLLW. It includes flats on State-owned land managed by the TGLO. This unit captures the intertidal complex of the bay, and is bounded by the towns of Gilchrist to the east and the Gulf beach of the Bolivar Peninsula to the south. This unit includes lands known as wind tidal flats that are infrequently inundated by seasonal winds.

BILLING CODE 4310–55–P

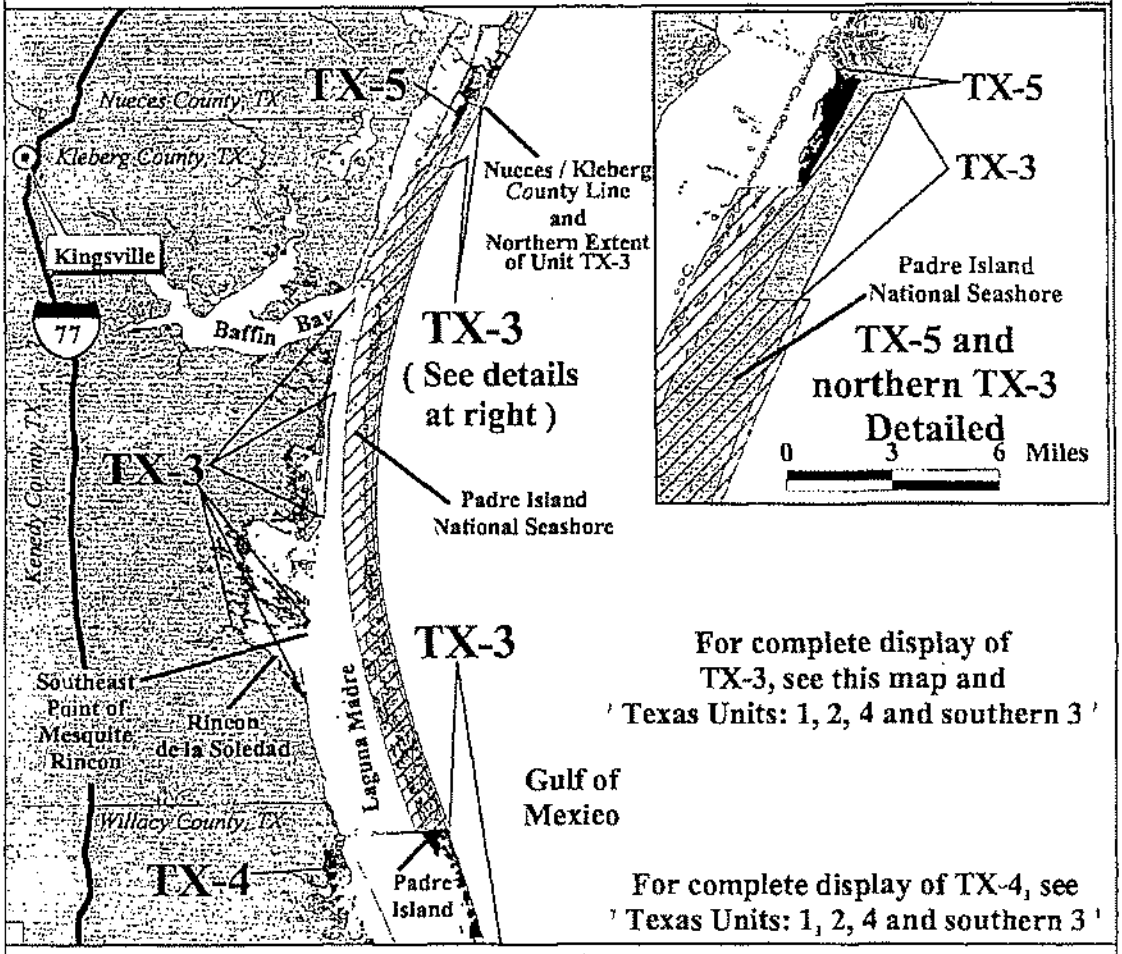
General locations of the designated critical habitat for the Wintering Piping Plover.



Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

Texas Units: 1, 2, 4 and southern 3

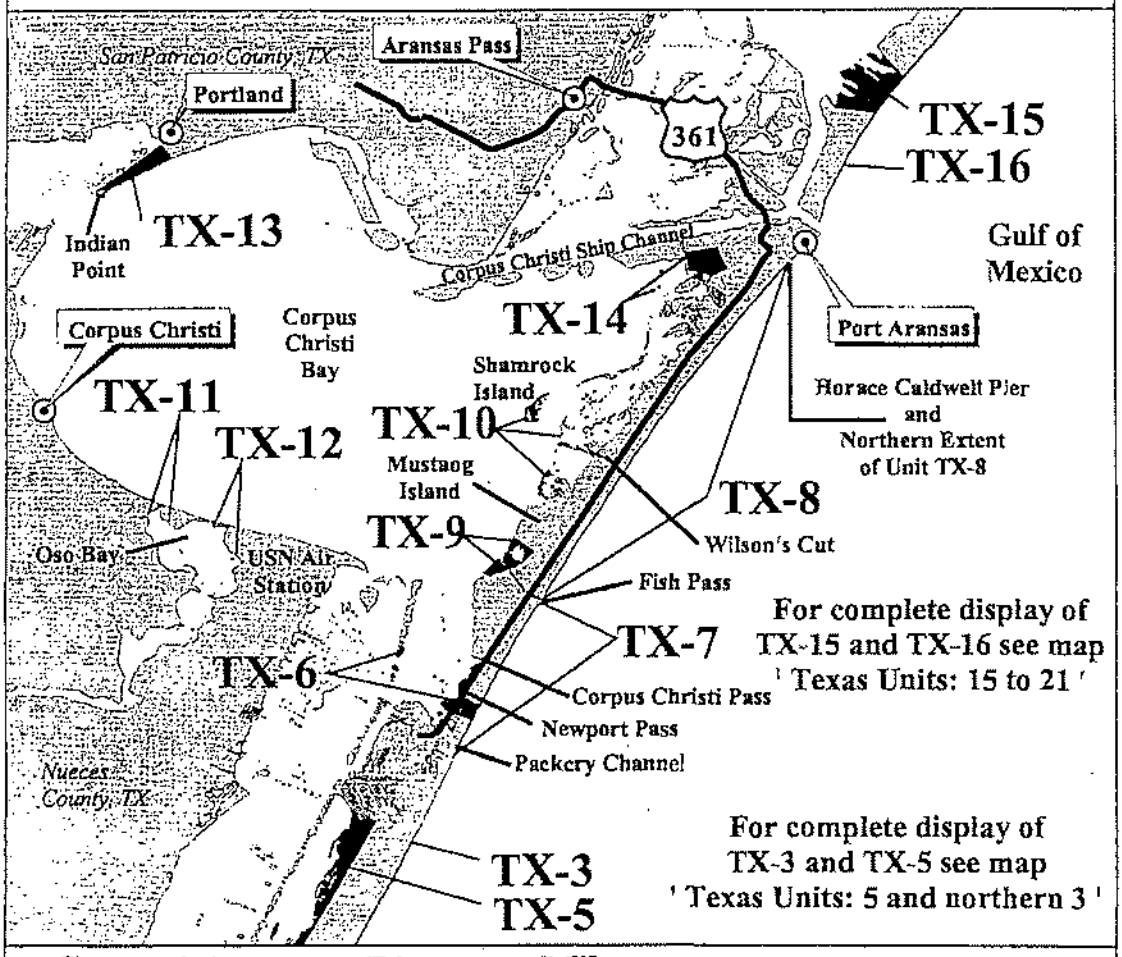
General locations of the designated critical habitat for the Wintering Piping Plover.

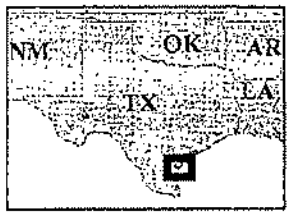


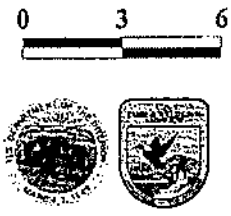
Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

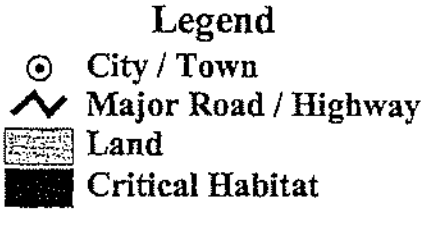
Texas Units: 5 and northern 3

General locations of the designated critical habitat for the Wintering Piping Plover.





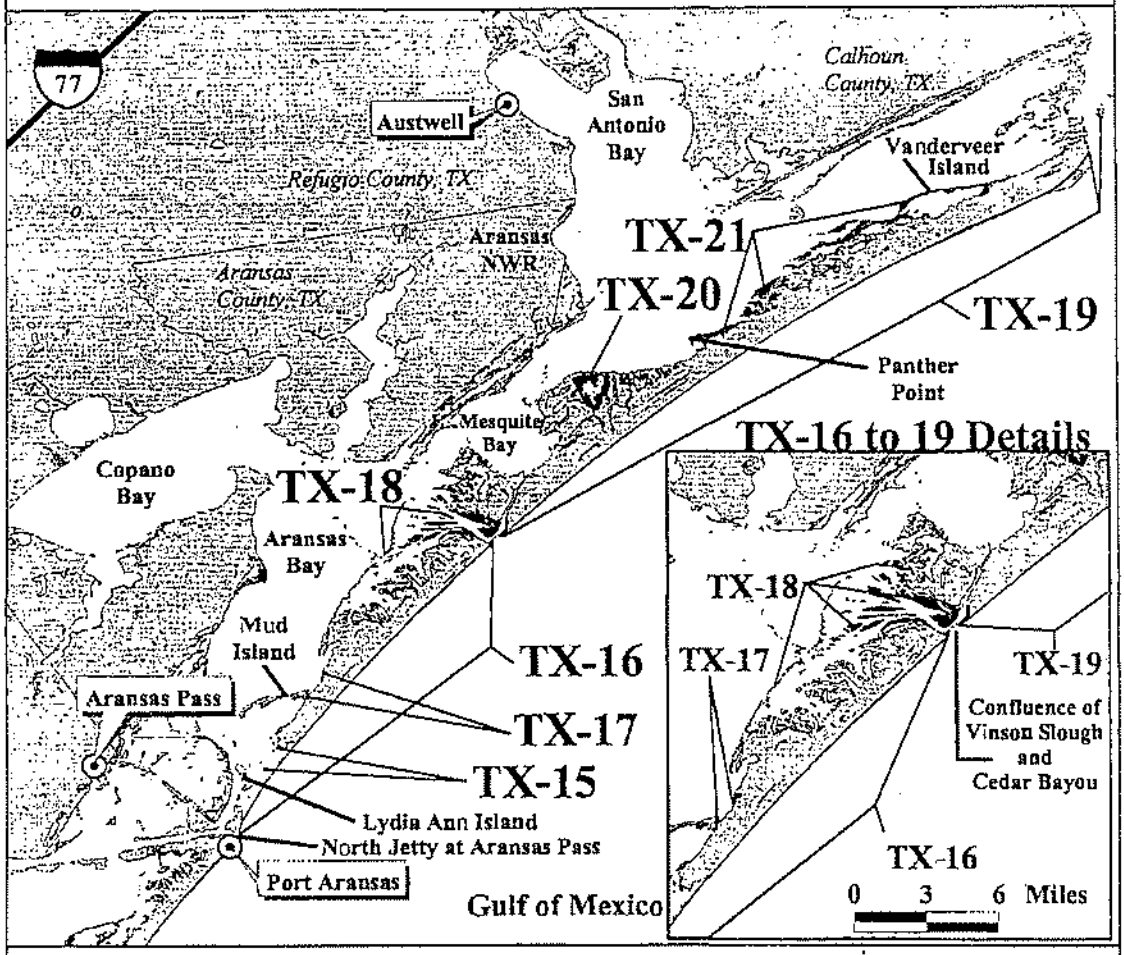




Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

Texas Units: 6 to 14

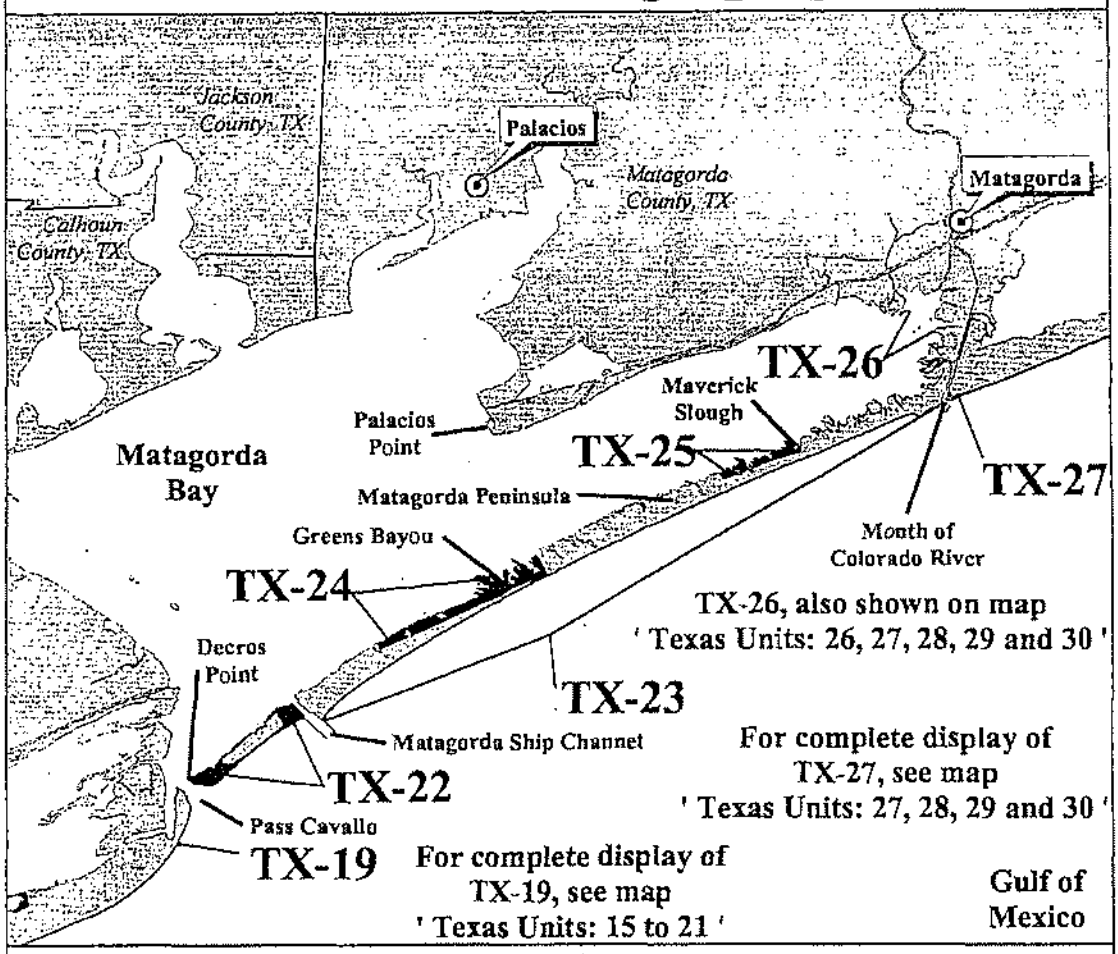
General locations of the designated critical habitat for the Wintering Piping Plover.



Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

Texas Units: 15 to 21

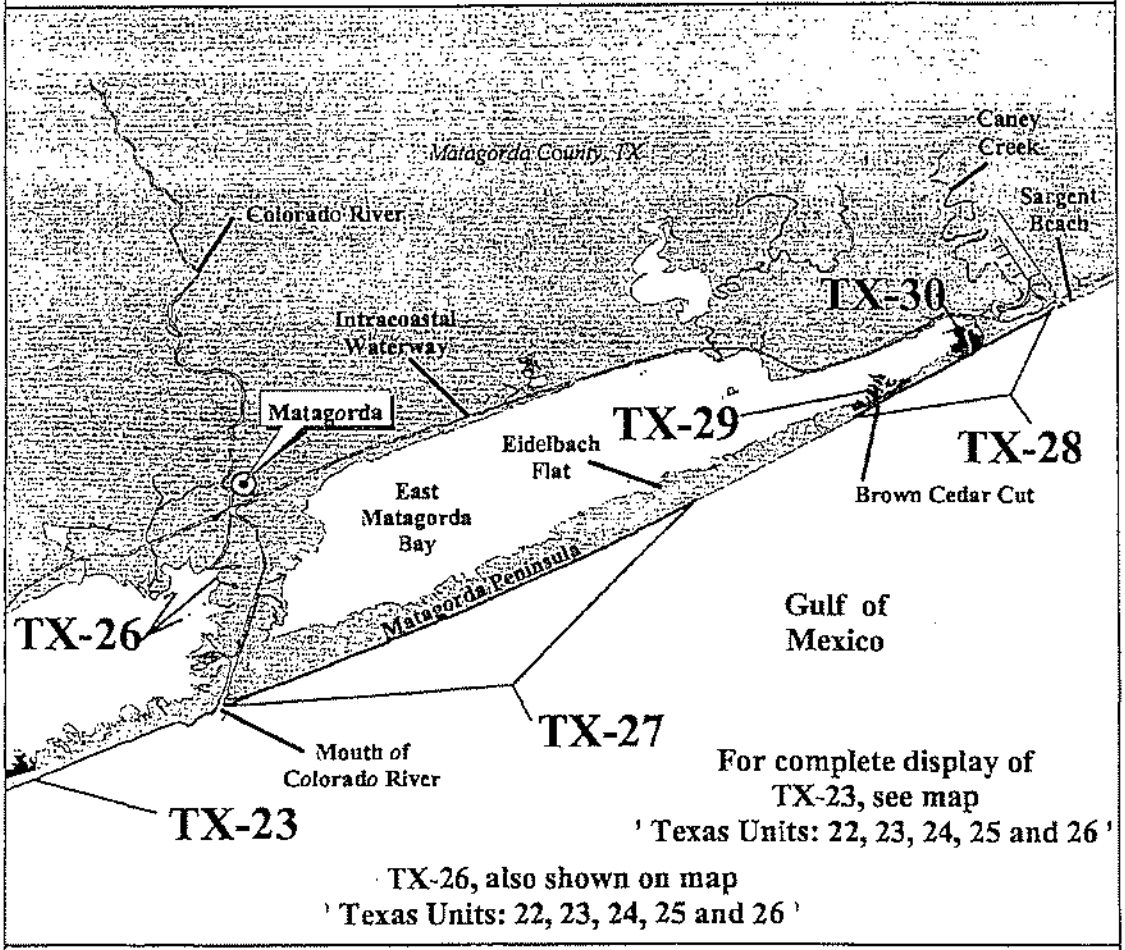
General locations of the designated critical habitat for the Wintering Piping Plover.



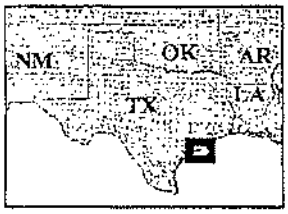
Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

Texas Units: 22, 23, 24, 25 and 26

General locations of the designated critical habitat for the Wintering Piping Plover.



General Area



Distance: Miles

0 7 14

N

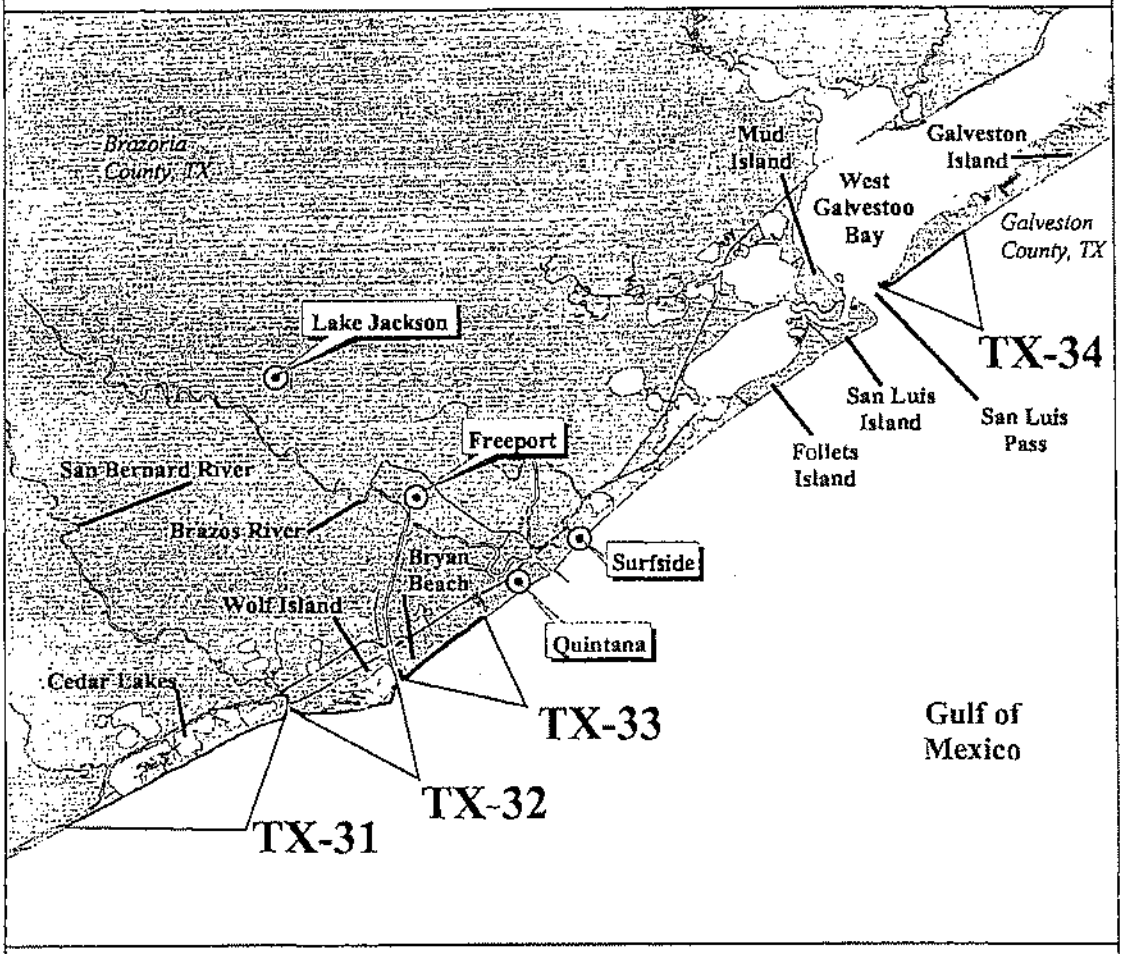
Legend

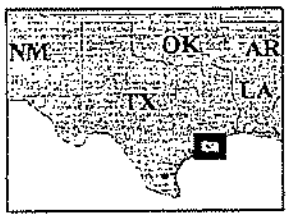
- City / Town
- Major Road / Highway
- Land
- Critical Habitat

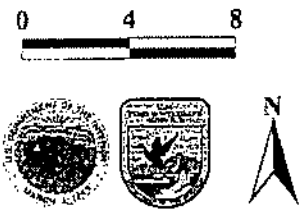
Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

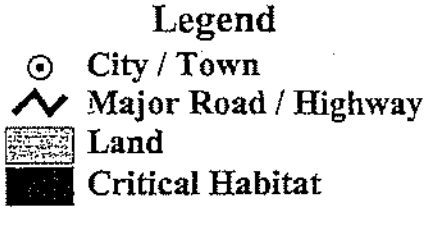
Texas Units: 26, 27, 28, 29 and 30

General locations of the designated critical habitat for the Wintering Piping Plover.



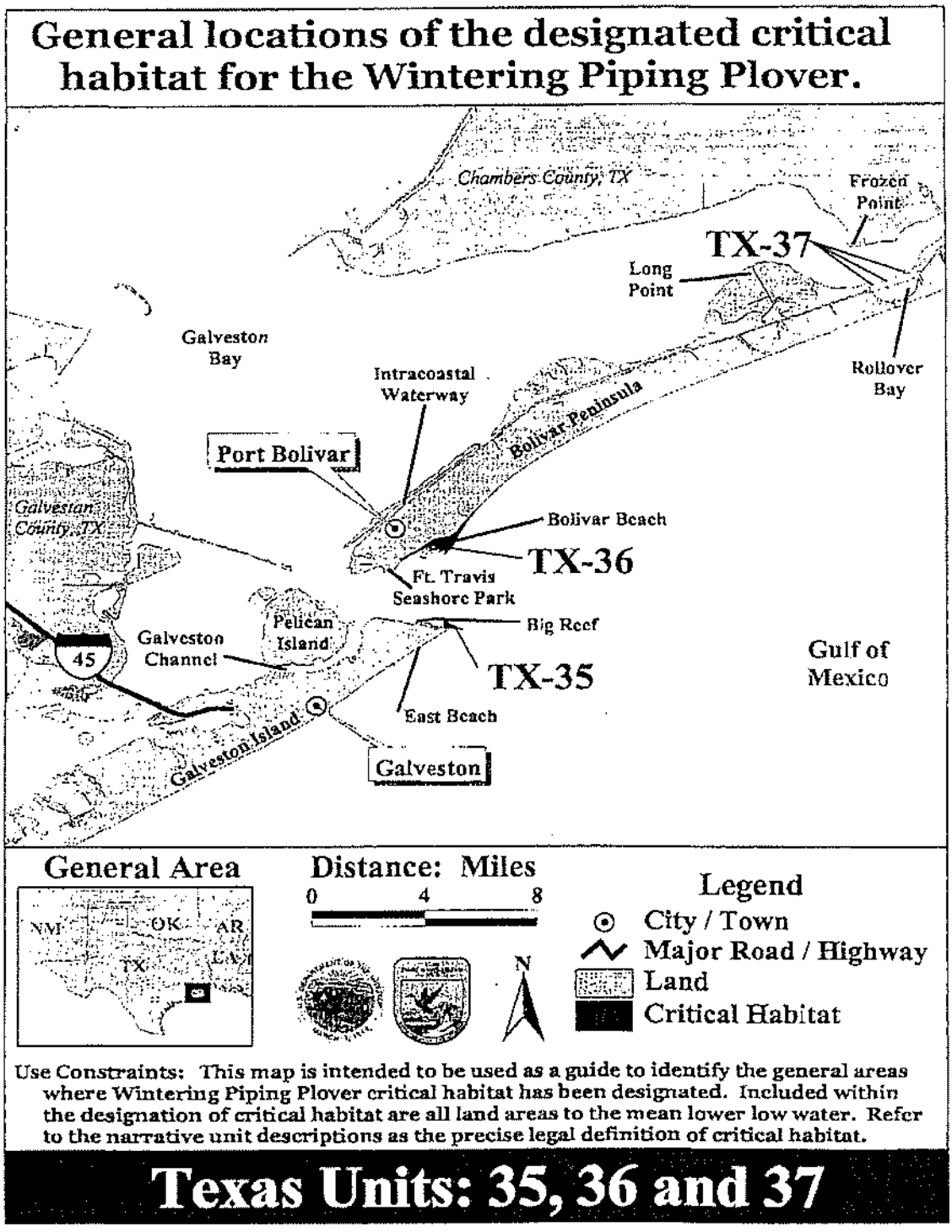






Use Constraints: This map is intended to be used as a guide to identify the general areas where Wintering Piping Plover critical habitat has been designated. Included within the designation of critical habitat are all land areas to the mean lower low water. Refer to the narrative unit descriptions as the precise legal definition of critical habitat.

Texas Units: 31, 32, 33 and 34



Dated: June 28, 2001.

Joseph E. Doddridge,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01-16905 Filed 7-9-01; 8:45 am]

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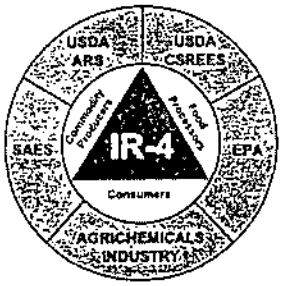

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Shanaz Bacchus
Biopesticide and Pollution Prevention Division
Room 910
1921 Jefferson Davis Highway
Arlington, VA 22202
(703)308-8097

March 7, 2003

RE: Aspergillus flavus AF-36 in or on Cottonseed
EPA Reg # 71693-R
PP# 8E5001

Dear Shanaz:

The undersigned, Dr. Michael Braverman, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial pesticide, Aspergillus flavus AF36 on behalf of the Arizona Cotton Research and Protection Council.

List of information Submitted

8570-1 Form

Data Waivers for Health Effects

Data Waivers for Environmental Effects

Research paper in preparation for Phytopathology by Garcia and Cotty "Aflatoxin Contamination of Commercial Cottonseed in South Texas"*

Efficacy data for AF-36 Texas as a public interest document*

* Note: The Aflatoxin and efficacy data are scientific data supplied by Peter Cotty which are intended for journal publication and should be considered Confidential Business Information until the are actually published

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

In regard to your questions concerning the use of AF-36 in Texas in proximity to water and the applicability of the waivers granted for Arizona to include Texas, the target for the product is cotton fields. In both Texas and Arizona, cotton is grown in a monoculture. While the overall environment outside of the fields may differ, cultural practices such as ditch and furrow irrigation make the cotton field environments quite similar for AF-36. Because AF-36 is applied as a granule the product should not drift outside of the cotton field. As shown in the attached article "Aflatoxin Contamination of Commercial Cottonseed in South Texas" there is a very high concentration of aflatoxin already present in cotton fields in the Gulf Coast Region. More specifically, "two sub areas showed recurrent high contamination which are immediately adjacent to the Gulf"(page 11). Like Arizona, a delayed harvest in Texas also results in increased aflatoxin contamination(page 15). It was concluded that the Gulf Coast areas of South Texas are areas that should have similar biological control programs to those used in Arizona(Page 17-18) Aflatoxin production in this area is due to the presence of Aspergillus flavus that produce the toxin. Aspergillus flavus is present on the cotton debris left behind in the field , cotton gin trash placed back on the field which totals about 10,000 pounds of plant debris per acre. Aspergillus flavus is also present in corn grown in the Texas Gulf Coast. The ubiquitous nature of Aspergillus flavus in the region means that all organisms including fish and other aquatic organisms are already exposed to Aspergillus flavus at quantities that vastly exceed the use of the product AF-36. The AF-36 strain is also already found in the soils and plant debris in Texas so there is not any new introduction of the organism. The purpose of applying the product AF-36 is not to increase the amount of Aspergillus population. The purpose is to change the proportion of the Aspergillus community that is composed of the AF-36 strain of Aspergillus. By changing the proportion of the Aspergillus flavus that consists of the AF-36 strain, there is a decrease of the toxin producing strains (such as the S strain). Therefore the use of the product AF-36 would not result in any greater exposure of fish or any other aquatic organism to Aspergillus flavus. In addition since AF-36 reduces aflatoxin production, the use of AF-36 should decrease the amount of aflatoxin exposure to fish and other aquatic organisms.

Yours very truly,

Michael Braverman

Michael Braverman, Ph.D.
Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator

IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71693-R	Shanaz Bacchus	[x] None [ ] Restricted
4. Company/Product (Name) Aspergillus flavus AF-36	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*
Arizona Cotton Research and Protection Council
3721 E. Wier Avenue
Phoenix, Arizona 85040-2933
[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Data waivers for ecological and health effects, efficacy data

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [ ] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [x] Other (Specify) Bulk boxes, bags
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [x] Label [ ] Container
4. Size(s) of Retail Container: Plastic bag 50lb, Bulk box/bag
5. Location of Label Directions: [x] On Label
6. Manner in Which Label is Affixed to Product: [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Larry Antilla	Staff Director	(602)438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received (Stamped)

2. Signature
3. Title: Staff Director
4. Typed Name: Larry Antilla
5. Date: 3-5-03

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

From: Michael Braverman (732)932-9575
IR-4 PROJECT/RUTGERS UNIVERSITY
TECHNOLOGY CENTRE OF NEW JERSEY
681 U.S. HIGHWAY #1 SOUTH
NORTH BRUNSWICK, NJ, 08902

REVENUE BARCODE

FedEx.

To: Shanaz Bacchus (703)308-8097
US EPA- BPPD Room 910
NINTH FLOOR-Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA, 22202450?

SHIP DATE: 10MAR03
WEIGHT: 2 LBS

Ref:

DELIVERY ADDRESS BARCODE(FEDEX-EDR)

FedEx STANDARD OVERNIGHT

TRK # 7915 4992 1170 FORM 0201

TUE
A1
Deliver by:
11MAR03

IAD

22202-VA-US 19 NDVA

Shipping Label: Your shipment is complete

Cancel shipment | Edit shipment information | Process another shipment | Go to

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

STUDY TYPE: Acute oral
USEPA OPPTS 885.3050
Acute toxicology
USEPA OPPTS 885.3550
Subchronic oral
USEPA OPPTS 885.3600
Chronic feeding
Guideline 152-50

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403 Therefore, the IR-4 Project is not requesting a waiver since the study has been completed and submitted. Since there were no adverse effects a acute toxicology study Tier II (885.3550) , Subchronic toxicology studty (USEPA OPPTS 885.3600) and chronic feeding studies (guideline 152-50) are not required.

STUDY TYPE: Acute dermal
USEPA OPPTS 885.3100
Primary dermal
USEPA Guideline number 152-34

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from acute dermal studies (OPPTS 885.3100). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects. Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of acute dermal testing.

WAIVER REQUEST JUSTIFICATION:

The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

3. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

4. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

5. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

6. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

7. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

8. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

10. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

11. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

12. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

13 The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Acute inhalation
USEPA OPPTS 885 3150

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity. Therefore, there is no need for a data waiver since these studies have been conducted.

Also please refer to MRID Number and Title of Previously submitted Volumes

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: I.V., I.C., I.P. injection
USEPA OPPTS 885.....
Guideline 152-33

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from injection studies (OPPTS 885.). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of injection testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. In an acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

3. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

4. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

5. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

6. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

7. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

8. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

10. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

11. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

12. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

13 The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Primary eye irritation
USEPA OPPTS 885.....
Guideline 152-35

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from primary eye iritation studies (OPPTS 885.....). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of primary eye irritation testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID

number 43972403

2. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

3. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

4. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

5. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

6. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

7. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

8. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

10. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

11. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

12. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

13 The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Hypersensitivity study, Hypersensitivity incidents
USEPA OPPTS 885.3400

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from hypersensitivity studies (OPPTS 885.3400). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of hypersensitivity testing.

WAIVER REQUEST JUSTIFICATION:

The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. the label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and

as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in

Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Immune response
USEPA OPPTS 885...
Guideline number I52-38.

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from immune response studies (OPPTS 885.....). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of immune response testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem.

Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and

Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Tissue culture studies
USEPA OPPTS 885...
Guideline number 152-39.

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from tissue culture studies (OPPTS 885.....). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of tissue culture testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus

AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150)

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. {2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Teratogenicity studies
USEPA OPPTS 885...
Guideline number 152-47, 152-53.

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from teratogenicity studies (OPPTS 885.....). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of teratogenicity testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared

by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100)

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Virulence enhancement studies
USEPA OPPTS 885...
Guideline number 152-48.

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from virulence enhancement studies (OPPTS 885.....). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of virulence enhancement testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

15. In over 15 years of laboratory studies involving hundreds of analyses, the results of the vegetative compatibility tests have not demonstrated any change in the organism.

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p.

{OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Mamalian mutagenicity studies
USEPA OPPTS 885...
Guideline number 152-49, 152-52.

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from mammalian mutagenicity studies {OPPTS 885.....}. The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of mammalian mutagenicity testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley,

peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Anilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Oncogenicity studies
USEPA OPPTS 885...
Guideline number 152-51.

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from oncogenicity studies (OPPTS 885.....). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, and that label language adequately protects from potential exposure and that actual field use under an EUP resulted in no reports of adverse effects.

The proposed uses of AF-36 on cotton is not expected to result in adverse effects . Therefore, testing is not considered necessary to assess the risks of AF-36 . The IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council requests a waiver of oncogenicity testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. An acute oral test was performed without any clinical signs or abnormalities. Refer to MRID number 43972403

2 An acute avian pulmonary toxicity test (MRID # 45798102) and acute pulmonary rat studies (MRID # 45739101, 45798101, 45798201) were conducted without infectivity/pathogenicity.

3. The label will require applicators and other handlers to wear personal protective equipment such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

4. Applications will involve ariel application by mixers/handlers who are licensed and trained to even handle restricted materials.

5. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre.

6. Since the product is applied as a granular formulation on wheat, exposure from drift will be minimal.

7. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment.

8. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

9. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

10. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

11. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is

often added back to the field and incorporated as organic matter.

12. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403. Therefore, man has been continually exposed to this organism due its natural occurrence in the environment and as part of crop production.

13. *A. flavus* AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to present) and in hand picked field plots (1989 to 1994) without report of any adverse health effects.

14. The use pattern of this product does not include uses on foods for direct human consumption

Also please refer to MRID Number and Title of Previously submitted Volumes

45739104 Antilla, L. ; Cotty. P. ; Braverman, M. (2002) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents: Lab Project Number 52B . Unpublished Study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

43972403 Shelton, L (1996) Acute Oral Toxicity Study in Rats:(Aspergillus flavus AF36):Final Report: Lab Project Number:M96AG84.6G31: Unpublished Study prepared by Microbiological Associates, Inc. 59 p.

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45798102 Rodgers, M. (2002) Toxicity/Pathogenicity to the Bobwhite Quail: Avian Inhalation Test Tier 1: Aspergillus flavus AF36: Lab Project Number: UAR 005: UAR 005/022336: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 21 p. {OPPTS 885.4100}

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary

Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

45798101 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/004: UAR004/014519/AC: PR 52B. Unpublished study prepared by Huntingdon Life Sciences Ltd. 53 p. {OPPTS 885.3150}

45798201 Blanchard, E. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Lab Project Number: UAR/006: UAR 006/023279/AC. Unpublished study prepared by Huntingdon Life Sciences Ltd. 61 p. {OPPTS 885.3150}

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin , AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris and for potential exposure to man.

References Cited: See volumes mentioned by MRID number.

STUDY TYPE: Avian Oral Testing, Tier I,
USEPA OPPTS 885.4050
Avian Pulmonary/Inhalation, Tier I,
USEPA OPPTS 885.4100

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project, Rutgers University on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council from avian oral toxicity/pathogenicity studies (OPPTS 885.4050). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, whose level in the environment will not significantly increase with the use of AF-36 and that actual field use under an EUP resulted in no reports of adverse effects in birds.

The proposed uses of AF-36 on cotton is not expected to result in increased exposure or adverse effects to birds. Therefore, testing is not considered necessary to assess the risks of AF-36 to avian wildlife. The IR-4 Project requests a waiver of avian oral testing.

An avian pulmonary study has already been conducted. Please refer to the following volume:

MRID 45798102 Aspegillus flavus isolate AF-36 -Toxicity /pathogenicity to the Bob White Quail Avian Inhalation Test Tier I

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the

commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . The current request is only for use in the on cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

7. AF-36 has been used under an EUP in Arizona without any known effects to any non-target organism

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45739103 Smith, D. Cotty, P. 2002 Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information

Increased environmental exposure to AF-36, due to use of the end-use product, (name of product), will be minimal: AF-36 spores are ubiquitous in nature .

Use of AF-36 will be limited to soil applications of the product on colonized wheat granules on cotton, thus minimizing direct exposure to birds. The seasonal migration away from the treated areas would reduce expose to endangered species such as plovers.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin which is adverse to all forms of wildlife, AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris.

References Cited: See volumes mentioned above by MRID number.

STUDY TYPE: Freshwater Fish Testing, Tier I
USEPA OPPTS 885.4200

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council for a data waiver from freshwater fish toxicity/pathogenicity studies (OPPTS 885.4200). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, whose level in the aquatic environment will not significantly increase with the use of AF-36. Off target exposure should be limited since it is applied in a granular form.

The proposed uses of AF-36 on cotton is not expected to result in increased exposure or adverse effects to freshwater fish. Any AF-36 that reaches aquatic systems, in the form of run-off, is expected to behave as it would in the wild.. Therefore, testing is not considered necessary to assess the risks of AF-36 to freshwater fish. The Arizona Cotton Research and Protection Council requests a waiver of freshwater fish toxicity/pathogenicity testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the

world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . The current request is only for use in the on cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

7. AF-36 has been used under an EUP in Arizona without any known effects to any non-target organism

8. Label language specifically prohibits direct application to water and adequately addresses the need to avoid drift to adjacent sensitive areas.

Increased aquatic exposure to Aspergillus flavus, due to use of the end-use product, AF-36, will be minimal:

Use of AF-36 will be limited to soil applications of the product on colonized wheat granules in cotton, thus minimizing direct exposure to fish. The use of granules as the application method will reduce the chance of off site movement of the product to bodies of water.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin which is adverse to all forms of wildlife, AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris. Therefore

the degree of aflatoxin contaminated soil and plant debris that could be transported from cotton fields should decrease.

* References Cited: See volumes mentioned above by MRID number.

STUDY TYPE: Wild Mammal Testing, Tier I
USEPA OPPTS 885.4150

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY : IR-4 Project on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council for a data waiver from freshwater fish toxicity/pathogenicity studies (OPPTS 885.4200). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, whose level in the aquatic environment will not significantly increase with the use of AF-36. Off target exposure should be limited since it is applied in a granular form.

The proposed uses of AF-36 on cotton is not expected to result in increased exposure or adverse effects to wild mamals. Any AF-36 that reaches terrestrial or aquatic systems, in the form of run-off, is expected to behave as it would in the wild.. Therefore, testing is not considered necessary to assess the risks of AF-36 to wild mammals. The Arizona Cotton Research and Protection Council requests a waiver of freshwater fish toxicity/pathogenicity testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop

debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . The current request is only for use in the on cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

7. AF-36 has been used under an EUP in Arizona without any known effects to any non-target organism

Increased aquatic exposure to Aspergillus flavus, due to use of the end-use product, AF-36, will be minimal:

Use of AF-36 will be limited to soil applications of the product on colonized wheat granules in cotton, thus minimizing direct exposure to animals. The use of granules as the application method will reduce the chance of off site movement of the product outside of cotton fields.

No evidence of adverse effects: Literature from databases are included in the cited volumes. While toxigenic strains produce aflatoxin which is adverse to all forms of wildlife, AF-36 displaces the toxigenic strain, thereby reducing their presence in soil and plant debris. Therefore the degree of aflatoxin contaminated plant debris available for exposure or consumption by wild mammals is also decreased.

* References Cited: See volumes mentioned above by MRID number.

STUDY TYPE: Nontarget Plant Studies, Tier I
USEPA OPPTS 885.4300

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY IR-4 Project on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council for a data waiver from non-target plant studies. The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, whose level in the environment will not significantly increase with the use of AF-36. Off target exposure should be limited since it is applied in a granular form.

The proposed uses of AF-36 on cotton is not expected to result in increased exposure or adverse effects to non-target plants. Any AF-36 that reaches terrestrial or aquatic systems, in the form of run-off, is expected to behave as it would in the wild.. Therefore, testing is not considered necessary to assess the risks of AF-36 to non-target plants. The Arizona Cotton Research and Protection Council requests a waiver of non target plant studies.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material.throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a

prominent part of the natural A. flavus community . The current request is only for use in the on cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/grain) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

5. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

6. AF-36 has been used under an EUP in Arizona without any known effects to any non-target Plants.

7. Cotton is grown as a monoculture. The application of this product as a granule should decrease the off site drift and potential exposure to non-target plants.

8. While many strains of Aspergillus flavus are found on plants, they are not considered plant pathogens.

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of Tolerance for Aspergillus flavus for use in Cotton Production

EPA has already determined that non target plants are not of concern. See Data Evaluation Record by Gail Tomimatsu dated April 24, 1996

* **References Cited** See MRID numbers above

STUDY TYPE: Nontarget Insect Studies, Tier I
USEPA OPPTS 885.4340
Honey Bee Studies
USEPA OPPTS 885.4380
ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council for a data waiver from non-target insect studies. The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, whose level in the environment will not significantly increase with the use of AF-36. Off target exposure should be limited since it is applied in a granular form.

The proposed uses of AF-36 on cotton is not expected to result in increased exposure or adverse effects to non-target insects. Any AF-36 that reaches terrestrial or aquatic systems, in the form of run-off, is expected to behave as it would in the wild.. Therefore, testing is not considered necessary to assess the risks of AF-36 to non-target insects. The Arizona Cotton Research and Protection Council requests a waiver of the non-target insect studies.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material.throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a

broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . The current request is only for use in the on cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

7. AF-36 has been used under an EUP in Arizona without any known effects to any non-target organism

8. A study o n Honeybees did not result in any adverse effects

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

45739102 Mayer, D.F. and L Antilla(2000) Honeybee Field Study of Aspergillus flavus AF 36 in Cotton.

EPA has already determined that non target insects are not of concern. See Data Evaluation Record by Doug Gurian-Sherman dated June 16, 1999 page 6

* References Cited: See data in volumes of MRID numbers listed above

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STUDY TYPE: Freshwater Aquatic Invertebrate Testing, Tier I
USEPA OPPTS 885.4240

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project on behalf of the Arizona Cotton Research and Protection Council

SUMMARY: The IR-4 Project is submitting a justification for a data waiver on behalf of the Arizona Cotton Research and Protection Council for a data waiver from Freshwater Aquatic Invertebrate Testing. The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil and plant colonizer, whose level in the environment will not significantly increase with the use of AF-36. Off target exposure should be limited since it is applied in a granular form.

The proposed uses of AF-36 on cotton is not expected to result in increased exposure or adverse effects to Freshwater Aquatic Invertebrates. Any AF-36 that reaches aquatic systems, in the form of run-off, is expected to behave as it would in the wild.. Therefore, testing is not considered necessary to assess the risks of AF-36 to non-target plants. The Arizona Cotton Research and Protection Council requests a waiver of Freshwater Aquatic Invertebrate Testing.

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material.throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . The current request is only for use in the on

cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are nussed during harvest and spillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

7. AF-36 has been used under an EUP in Arizona without any known effects to any non-target organism

8. Label language specifically prohibits direct application to water and adequately addresses the need to avoid drift to adjacent sensitive areas.

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

EPA has already determined that freshwater and marine aquatic invertebrates are not of concern. See Data Evaluation Record by Doug Gurian-Sherman dated June 16, 1999 page 5

* References Cited: See volumes mentioned by MRID number

STUDY TYPE: Estuarine and Marine Animal testing, Tier I
USEPA OPPTS 885.4280

ACTIVE INGREDIENT: Aspergillus flavus AF-36

SYNONYMS: AF-36

REQUESTED BY: IR-4 Project on behalf of the Arizona Cotton Research and Protection Council

WAIVER REQUEST JUSTIFICATION:
The waiver request is based on the following rationales:

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material.throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . The current request is only for use in the on cotton in the states of Arizona and Texas. Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and spillage, and gin trash which is

often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

7. AF-36 has been used under an EUP in Arizona without any known effects to any non-target organism.

8. The State of Arizona does not contain Marine or Estuarine areas and the cotton growing area adjacent to these areas are limited. Label language specifically prohibits direct application to water and adequately addresses the need to avoid drift to adjacent sensitive areas.

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of Tolerance for Aspergillus flavus for use in Cotton Production

EPA has already determined that marine organisms are not of concern. See Data Evaluation Record by Doug Gurian-Sherman dated June 16, 1999 page 6 .

* References Cited: See volumes mentioned by MRID number

MEMORANDUM

SUBJECT: BPPD Review of Information Submitted by USDA Southern Regional Research Center/IR-4 for an Experimental Use Permit for *Aspergillus flavus* AF36; Request for Waiver for Non-Target Plant Testing (Submission No.S502127; DP Barcode No:D224186; ID No:-69224-EUP-R, Chemical ID No.: 006456) (MRID #s: 437634-03 and 437634-05; 1 volume *sans* MRID#," Volume 6")

TO: Shanaz Baccus, Regulatory Action Leader
Biological and Pollution Prevention Division (7501W)

FROM: Gail S. Tomimatsu, Ph.D., Plant Pathologist APR 24 1996
Biological and Pollution Prevention Division (7501W)

THROUGH: Robert I. Rose, Ph.D., Entomologist April 24, 1996
Biological and Pollution Prevention Division (7501W)

ACTION REQUESTED:
BPPD has been asked to review product performance, (MRID # 437634-05), safety data (MRID #437634-03) and published information (No MRID #) regarding the ecology of *Aspergillus flavus* AF36 and to waive non-target plant testing for experimental application on a 3-year cumulative 1,120 acres of cotton in Yuma County, Arizona. The submitted materials consisted of publications from peer-reviewed journals or books and provided rationale for further testing for Section 3 registration. Data evaluation records for these submissions are not forthcoming.

CONCLUSION/RECOMMENDATIONS:
The information submitted is considered adequate to waive data requirements for non-target plants (Subdivision M, FIFRA Guideline 154A-22). Of concern is unintended exposure to non-target mammalian and avian species, and honeybees. *Aspergillus flavus* could be considered as an infrequent, and occassional pathogen in the aspergillosis-related respiratory afflictions in birds and domesticated mammals, although the reported incidents of aspergillosis in immunocompromised, or very young, or otherwise stressed individuals seem to be increasing. Occassional incidents of stonebrood (caused by *A. flavus*) in honeybee colonies have been reported. These studies will not be required for the EUP, however for Section 3 registration, we recommend an avian toxicity/pathogenicity study with subsequent post-mortem histopathology, using the Northern Bobwhite (*Colinus virginanus*) as the test bird. We may also require wild mammal toxicity/pathogenicity and honeybee studies after consideration of appropriate testing protocols. Appropriate scientific staff in the Agency should be consulted prior to conducting the studies.

BACKGROUND:

According to the submitted materials, *Aspergillus flavus* AF36 is a strain of *A. flavus*, an indigenous, soil fungus in cotton fields; it is a name for a "genetic group" with similar morphological and physiological characteristics that have not produced aflatoxins (=atoxigenic isolates) thus far, in extensive laboratory, greenhouse and treated cotton and corn evaluations. Within the same agricultural field, or even on an individual plant, the overall tendency of the resident *Aspergillus* spp. population to produce aflatoxins is highly variable. Published literature characterize *A. flavus* populations as highly complex, and composed of strains that differ morphologically, physiologically, and genetically. Members of the *Aspergillus* genus are common air and soil residents, capable of surviving hot and dry conditions; 37 °C is the optimum temperature for growth.

In field studies of cotton and corn, atoxigenic strains of *A. flavus* (e.g., *A. flavus* AF36) essentially 'displaced' toxigenic strains of the same fungus, and reduced overall aflatoxin levels. A single application of the microbial pesticidal product, sterile wheat seed colonized by *A. flavus* AF36 should be applied to the surface of the soil, under the plant canopy through a cultivator mounted granular applicator; followed by furrow irrigation within 3 days of treatment . - -

Aflatoxins are toxic, carcinogenic metabolites produced by the ubiquitous *A. flavus* Link:FR and *A. parasiticus* Speare during the infection and decay of developing and mature crops. Aflatoxin contamination of cottonseed is most severe in seed from bolls damaged by the pink bollworm in the irrigated western desert valleys of Arizona and southern California. Conventional methods for the prevention of contamination are not reliable on a commercial scale for any of the affected crops.

DISCUSSION OF SUBMITTED MATERIALS:

The published studies and information contained in Volume 6 of 7: (No MRID #) Aspergillus flavus isolate AF36, Plant Studies, Request for Waiving of the Requirement for Testing, Subdivision M, Guideline 154A-22 are considered adequate to waive data requirements for non-target plants. Submitted materials attest to the virtual ubiquity and natural occurrence of toxigenic and atoxigenic strains of *A. flavus* on a wide variety of live and decaying materials.

The published studies and information contained in Volume 4: (MRID # 437634-03) Aspergillus flavus isolate AF36 - Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirement of a Tolerance for Aspergillus flavus for Use in Cotton Production, and in Volume 7: (MRID # 437634-05): Aspergillus flavus isolate AF36, Product Performance Data raise concerns for adverse risks to nontarget mammalian and avian species and honeybees. Although the vast majority of cases of deep infections of aspergillosis are caused by *A. fumigatus*, other thermotolerant species, such as *A. flavus* can be involved in such infections, and will grow well at blood temperatures. Lesions reminiscent of all the human forms of aspergillosis have been described in other mammals, though the presentation

is often different. Common sinus infections have been described for dogs and horses; some of these respiratory ailments have resulted in equine fatalities from rupture of the carotid artery, which lies close under the epithelium lining the guttural pouch (i.e., an air-filled diverticulum of the eustachian canal). Outbreaks of acute aspergillosis (caused by *Aspergillus* spp.) were reported in the pulmonary tracts of very young pigs (less than 3 weeks of age) and sheep. Another form of acute aspergillosis may be involved in fetal abortion of cattle, sheep, horses and pigs. Invasive aspergillosis caused by *A. terreus* infections in the bones of spine and limbs, and kidneys and spleen were reported in adult German Shepherds. An unknown factor in this canine breed may be contributing towards reduced immunoprotection comparable to human immunosuppression.

Aspergilli have long been known to infect the lungs and air-sac systems of passerine birds, reportedly causing two major clinical diseases: acute pneumonia in young chicks and chronic pulmono-visceral disease in older birds. Chronic infections may lead slowly to reduction in respiratory function and may spread to the other viscera in older birds, as well as a few captive wild birds. *Aspergillus flavus* is reportedly pathogenic on honeybees (*Apis mellifera*), silkworm (*Bombyx mori* L.), domestic housefly (*Musca domestica nebulo* Fabricius), cecropia moth (*Platysamia cecropia L.*) and the mound-building termite (*Odontotermis obesus*).

Therefore, an avian toxicity/pathogenicity study with post-mortem histopathology will be required for FIFRA Section 3 registration. Wild mammal and honeybee testing may also be required. Appropriate Agency scientists should be consulted prior to conducting the studies.

The intended experimental use of *A. flavus* AF36 in the restricted cotton acreage (cumulative total of 1,120 A over a 3-yr period) of Yuma County, Arizona pose minimal to no exposure concerns for endangered species reported for that region. The clapper rail feeds on aquatic invertebrates in water marshes; birds of prey such as the peregrine falcon and bald eagle and the wild mammal, pronghorn antelope would not be expected to enter cotton fields.

DATA EVALUATION REPORT

Reviewed by:	Doug Gurian-Sherman, Ph. D., Plant Pathologist 6/18/99 Biopesticides and Pollution Prevention Division
Secondary Reviewer:	Gail Tomimatsu, Ph.D., Plant Pathologist, 6/23/99 Biopesticides and Pollution Prevention Division

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STUDY TYPE:	Non-target Organism Environmental Safety Requirements, Waiver Request for Subdivision M, Guidelines: 154A-16 - 24
MRID NO:	None
TEST MATERIAL:	*Aspergillus flavus* isolate AF36, provided by Sponsor
STUDY NO:	IR-4 PR No. 52B
SPONSOR:	IR-4 Project, Technology Center of New Jersey Rutgers University 681 U.S. Highway No. 1 South North Brunswick, NJ 08902-3390
TESTING FACILITY:	Southern Regional Research Center USDA/ARS P.O. Box 19687 New Orleans, LA 70179
TITLE OF REPORT:	Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information (Volume 6 of 7)
AUTHOR(S):	Dr. Peter J. Cotty (USDA/ARS) Southern Regional Research Center USDA/ARS P.O. Box 19687 New Orleans, LA 70179; Dr. W.L. Biehn (IR-4), IR-4 Project, Technology Center of New Jersey Rutgers University 681 U.S. Highway No. 1 South North Brunswick, NJ 08902-3390;

Mr. Larry Antilla
Arizona Cotton Research and Protection Council
2403 W. Huntington Dr., Suite 101
Tempe, AZ 85282-3166

STUDY COMPLETED: June 25, 1998

CONFIDENTIALITY CLAIMS: None.

CLASSIFICATION: Acceptable for EUP (see additional data requirements necessary for full registration)

Study Summary:
A. flavus is indigenous to the areas considered for use of AF36, where it is a common soil inhabitant. AF36 is a naturally occurring strain (MRID Nos. 43763401, 4390001). Use of AF36 will not change the amount of *A. flavus* in the environment (see appendix IV). The amount of organic matter added by the AF36 treated wheat seed (10 Lbs/A) is small compared to the amount of organic crop matter (appendix V) naturally colonized by *A. flavus*. *A. flavus* is commonly found in poultry feed, so exposure to poultry already occurs by this route. Assays of wheat seed from Arizona not treated with AF36 shows 100% *A. flavus* colonization in 1997 and 38% in 1998, therefore exposure from wheat fields already occurs (see appendix III). Use of AF36 in Arizona constitutes a minor use, and should be subject to regulatory relief. Lack of increased exposure applies to all of the required studies below.

Test Methods:
Most of the current study consists of summaries of data and methods are not included. Bird usage information by Chuck Youngker consists of anecdotal observations of birds and personal knowledge of cropping practices.

Occurrence of *A. flavus* on wheat seeds was determined from samples collected from wholesalers of Arizona wheat or from soil just after harvest. Control seed was from Hereford, TX. Wheat seeds were plated on Rose-Bengal agar (15-25 per plate), incubated at 31 °C for 5 to 7 days, and examined for *A. flavus* conidiophores.

Results Summary:
In addition to the above argument, avian oral toxicity/pathogenicity studies, (guideline number 154A-16), should be waived because bird exposure will not be increased. Observation of bird usage by cotton producer Chuck Youngker suggests that cotton fields are not preferred bird habitats and that birds are not attracted to them (appendix VII). Cotton fields are inhospitable after application in early June and provide little food,

even with the application of treated wheat seed at 10 lbs/A, especially since wheat fields with more wheat seed are available.

Poultry, which are highly susceptible to aspergillosis, are frequently exposed to fungi in enclosed in confinement houses. This exposure includes *Aspergillus* species. *A. fumigatus*, rather than *A. flavus,* is most commonly the cause of aspergillosis. Since pulmonary exposure will not be increased due to use of AF36, avian pulmonary toxicity/pathogenicity studies, guideline No. 154A-17, should be waived.

No arguments are presented to support waiver of wild mammal testing, guideline 154A-18. However, this study is included in the request (see title). Guideline study 154A-18 is conditionally required. Additional concerns will be addressed by pulmonary toxicity/pathogenicity studies being required for section 3 registration for human health effects.

A. flavus exposure of fish is not expected to be increased by the use of AF36 and fish are not reported to be susceptible to *A. flavus*, therefore freshwater fish toxicity/pathogenicity tests, guideline No. 154A-19, should be waived.

Since no adverse affects due to *A. flavus* have been reported for aquatic invertebrates, and exposure is expected to be minimal, test guidelines 154A-20 should be waived.

Waiver of estuarian and marine animal testing, guideline 154A-21, has not been specifically addressed but is included in the waiver request (see title). This study is typically only conditionally required.

Plant studies, guideline No. 154A-22, have been addressed in previous volume 6 titled "*Aspergillus flavus* Plant Studies - Request for Waiving the Requirement for Testing" (see appendix II). This volume is resubmitted.

A. flavus has been isolated from a number of insects (MRID No. 437634-03), but is not reported generally as an insect pathogen, therefore non-target insect testing, guideline 154A-23, should be waived.

Honey bees are not associated with cotton production, and "stone brood" caused by *A. flavus* is rare and of minor importance. Therefore guideline 154A-24 should be waived.

Study Author's Conclusions

Based on the above considerations, all of the listed non-target organism tests should be waived.

Reviewer's Conclusion

Data submitted by Applicant and other published data agree that *A. flavus* is ubiquitous

in the Arizona desert. In addition to presence, levels of natural occurrence compared to treated fields must be considered in determining risk to susceptible organisms. Applicant presents summary data concerning soil populations of *A. flavus* prior to treatment and one year after application (page 43/70). These data suggest that populations of *A. flavus* are not increased by treatment one year after application compared to populations before treatment.

Applicant also presents data on the levels of propagules on treated and untreated crop matter and cottonseed in treated and untreated fields (page 45/70 and 46/70). The amounts of *A. flavus* on the crop was determined at maturity, when populations are typically highest. These data also indicate that populations of *A. flavus* are not significantly affected by application of the product to cotton fields.

However, while adequate to support the requested EUP, measurement of levels of total *A. flavus* on the crop at maturity and in the soil one year after application should continue for at least one season (depending on the results obtained). These measurements should continue because of the possible pathogenicity of the active ingredient, the heavy reliance of the Applicant on exposure and natural occurrance data, and especially the high degree of variability of the data, which is typical for measurements of this type.

Applicant has also argued elsewhere (Vol. 1, completed 12/8/98, reviewed below) that amounts of *A. flavus* in the soil are not increased during the growing season, nor at crop maturity. This data is supportive, but not conclusive, as explained below.

Applicant presents several arguments based on the relative biomass of the added product compared to the amount of biomass available to *A. flavus* already present in the environment, to suggest that the small amount of added AF36 will not increase overall *A. flavus* in the Arizona environment. These arguments cannot substitute for actual measurements of *A. flavus*. For example, it is not shown how good a growth substrate wheat is compared to other biomass. In addition, the product is prepared under conditions optimized for high inoculum production that may not typically occur in the field. Also, data are insufficient to demonstrate the amount of inoculum found on naturally occurring or agriculturally produced biomass for comparison with treated wheat seed.

Measurement of inoculum or propagule levels one year after application may not reflect higher transient amounts. For example, it is known that amounts of soil borne propagules increase dramatically in July and August. One year later, the nutritional substrate provided by the wheat seeds and other biomass may have been depleted, supporting lower amounts of AF36. Likewise, amounts of propagules on the crop may reflect saturation of the intrinsic carrying capacity of that biomass. Propagules above that amount produced by introduced inoculum may therefore not be reflected in these

measurements. Therefore, as detailed in the review below, propagule measurements performed at crop maturity must be conducted during the course of the EUP.

A. flavus is a known bird pathogen, causing invasive aspergillosis, often fatal when it occurs. Waiver of avian testing requirements is proposed based on exposure arguments discussed above and arguments that birds do not widely use cotton fields as habitat. Some of this information is of an anecdotal nature (e.g. as supplied by cotton producer Chuck Youngker), which is insufficient to base a waiver approval. Arguments that better food sources are available and that cotton fields are unsuitable habitats cannot substitute for actual data of bird usage of Arizona cotton fields. For example, while cotton is heavily managed, which Applicant argues would dissuade the presence of birds, there are still periods where there is little human activity in the fields. Cultivation, etc., may prevent or disrupt nesting, but may not prevent foraging by birds nesting elsewhere. Also, while humidity may be high, some birds may be attracted to the water supplied by irrigation. Actual bird census data, reviewed below, reveals a substantial presence of birds in Arizona cotton fields.

Applicant also points out that oral exposure is not noted in the literature as the usual route of infection of birds. However, oral infectivity cannot be ruled out, especially in wild species. Many studies do not examine route of exposure and assume that infection is respiratory due to infection of respiratory tissues.

Feeding is an important likely route of exposure for birds eating treated wheat seed. Therefore, oral avian toxicity/pathogenicity studies must be performed on quail before full registration can be approved.

Arguments for waiving avian pulmonary testing are also based on natural exposure. In addition, Applicant argues that poultry are susceptible in containment houses, where exposure is high. However, the infectivity in wild populations may not be well documented. As noted above and addressed below, transient levels of AF36 relative to untreated fields are currently not known with confidence. Such measurements have a high level of variability and may vary from year to year. In addition, nothing is known about the pathogenicity of AF36, and Applicant's isolate of AF36 in particular, which might be more or less virulent than other strains. Therefore, avian pulmonary tests must be performed on quail and preferably a second test species. However, since preliminary indications (see review below) suggest that transient levels of AF36 will not be significantly increased with treatment, these tests are required for full registration and may be performed concurrently with the EUP.

Concerns about freshwater and marine aquatic invertebrates and fish are adequately addressed by Applicant's arguments, and by the lack of exposure due to the location of application. Therefore, test requirements for these organisms may be waived.

Non-target plant testing has been adequately addressed by a prior EUP review (Tomimatsu and Rose, Memorandum dated 24 April1996, DP barcode No. D224186). Exposure will be highest in the cotton fields where non-target plant concerns will not apply. Exposure beyond the field is not expected to increase to levels of concern for non-target plants. Therefore, this test requirement may be waived, and the resubmitted study "*Aspergillus flavus* Plant Studies - Request for Waiving the Requirement for Testing" (completed July 31, 1995), will not be further reviewed here.

Applicant argues that *A. flavus* infection of honey bees, causing "stone brood", is a rarely reported occurrence and is considered a pathogen only of weakened hives. Applicants also argue that honey bees are not associated with cotton production. However, literature indicates that while cotton is not likely to be a preferred food source for honey bees, they will forage in cotton flowers, especially if preferred sources are not available (see e.g. ref.1). In addition, other bees, such as solitary species, are important pollinators in Arizona, and also visit cotton (see reference). Pathogenicity of species other than honey bees is unclear, but must be considered a distinct possibility given honey bee pathogenicity. In addition, as noted above, transient exposure considerations are currently unresolved, and the pathogenicity of AF36 is unknown. Therefore honey bee hive testing must be performed prior to full registration. Alternatively, Applicant may propose other local species of bee larva as an alternative for honey bees.

Applicant's arguments and data concerning other non-target insects are adequately addressed, and therefore other non-target insect testing may be waived.

Arguments or data supporting waiver of marine organism and wild mammal tasting have not been addressed. However, Applicant has included the guideline numbers for these tests in the title of this study. Therefore, it is assumed that waiver of these tests is desired. Wild mammal testing has been partially satisfied by prior oral toxicity studies, and will be adequately addressed by required human safety tests for pulmonary toxicity/pathogenicity. Exposure to marine organisms is not expected to occur with this use of AF36. Therefore, these studies may be waived. However, Applicant should formally request waiver of these studies. 6 In addition, the methods for assaying environmental levels AF36 and *A. flavus* should be submitted where this has not already been done.

Reference:

D. Eisikowitch and G. M. Loper (1984) Some aspects of flower biology and bee activity on hybrid cotton in Arizona, USA. J. Apicultural Res. 23(4), 243-248

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

August 8, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266 A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: Aspergillus flavus AF-36 Arizona Cotton Research and Protection Council Company Number 71693

Dear Dr. Andersen:

Enclosed please find our application for Pesticide Registration for the above subject product. Enclosed also are: Proposed label (5 copies); confidential statement of formula; certification with respect to citation of data statement, etc.

In support of this application, please refer to the petition entitled "Aspergillus flavus AF-36 Tolerance Exemption in or on Cotton".

This petition was submitted by IR-4.

As per PR Notice 88-4, the registration of the above use is exempt from fees.

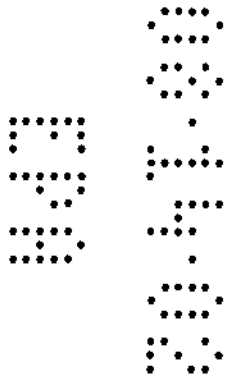
Sincerely,

Larry Antilla
Director

Registration Volume

Aspergillus flavus AF-36

TABLE OF CONTENTS PAGE NUMBER



United States Department of Agriculture
Agricultural Research Service
Mid South Area Southern Regional Research Center
1100 Robert E. Lee Boulevard
P.O. Box 19687
New Orleans, Louisiana
70179-0687

Dr Janet Andersen
Biopesticide and Pollution Prevention Division
c/oDocument Processing Desk
Office of Pesticide Programs 7504C
U. S. Environmental Protection Agency
Room 226 , Crystal Mall 2
Arlington, Virginia 22202

July 30, 2002

RE: Aspergillus flavus AF-36
Section 3 registration

Dear Dr Andersen:

This letter authorizes the Environmental Protection Agency to refer to the USDA/ARS Southern Regional Research Center data on *Aspergillus flavus* when considering the application for registration for *Aspergillus flavus* AF-36 submitted for the Arizona Cotton Research and Protection Council by the fR-4 Project. This includes all data previously submitted for both the Experimental Use Permit and Section 3 registration.

Sincerely,

Peter J. Cotty, Ph.D.
Research Plant Pathologist

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

August 8, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266 A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: Aspergillus flavus AF-36 Arizona Cotton Research and Protection Council Company Number 71693

Dear Dr. Andersen:

This letter authorizes the Environmental Protection Agency to refer to the Arizona Cotton Research and Protection Council data on Aspergillus flavus when considering the application for registration for Aspergillus flavus AF-36. This includes currently submitted data by USDA/ARS and the IR-4 Project in addition to data and waivers previously submitted for the Experimental Use Permit. We also authorize the IR-4 Project to act as our representative.

Sincerely,

Larry Antilla,
Director

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States Environmental Protection Agency Washington, DC 20460

[X] Registration [ ] Amendment [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 71693
2. EPA Product Manager: S. BACCHUS
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): ASPERGILLUS FLAVUS AF36
PM#
5. Name and Address of Applicant (Include ZIP Code)
Arizona Cotton Research & Protection Council
3721 E. Wier Avenue
Phoenix, Arizona 85040-2933
[X] Check if this is a new address
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Superceds previous submission dated June 26, 1998
Data (MRID) numbers from previous section 3 submission and Experimental Use Permit submission are cited.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic Bag [ ] Glass [ ] Paper [X] Other (Specify) Bulk Bags Bulk Boxes
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) Retail Container: Plastic Bag: 50 lbs. Bulk Bag/Box: 1000-3000 lbs
5. Location of Label Directions: [X] On Label
6. Manner in Which Label is Affixed to Product: [X] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
LARRY ANTILLA	STAFF DIRECTOR	(602) 438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature
3. Title: STAFF DIRECTOR
Typed Name: LARRY ANTILLA
5. Date: 5-5-02
6. Date Application Received [Stamped]

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product Chemistry Data

Guideline 151-10, 151-11, 151-12, 151-13, 151-15, 151-16, 151-20, 151-21, 151-22, 151-25, 151-26

Please refer to the following volumes:

MRID Number and Title of Previously submitted Volumes

44626101 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 -Analysis of samples, Certification of Ingredient limits, :Amendment Number 2 to MRID No. 43763402 .

44713701 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 - Amended Manufacturing Process -- Amendment number 3.

44597001 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID 43763401

43763401 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.

43990001 Cotty, P. (1996) Aspergillus flavus isolate AF 36 Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No 1 to MRID 43763401.

43763402 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.

43972401 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits. Amendment No. 1 to MRID No. 43763404

PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS
Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

AGRICULTURAL USE DIRECTIONS
The pesticide should only be applied when the potential for drift to adjacent environmentally sensitive areas is minimal . May be applied to irrigated cotton fields.

RE-ENTRY STATEMENT
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, longsleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21CMixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

GENERAL USE PRECAUTIONS
Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.
PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.
CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

ASPERGILLUS FLAVUS AF36

FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

ASPERGILLUS FLAVUS AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied just prior to first bloom, ASPERGILLUS FLAVUS AF36 competes with strains of Aspergillus flavus that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop. Thus, ASPERGILLUS FLAVUS AF36 reduces the quantity of aflatoxin contaminating the crop.

Active ingredient: *Aspergillus flavus* strain AF36 (3,000 CFU/g)	0.0008%
Wheat seeds	99.9992%
Total:	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For application to cotton to control aflatoxin producing strains of *Aspergillus flavus*.

ASPERGILLUS FLAVUS AF36 has been shown to reduce aflatoxin contamination of cottonseed by competitively excluding aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.
3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of ASPERGILLUS FLAVUS AF36.
5. Use 10 lbs of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT
To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

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PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS
Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

AGRICULTURAL USE DIRECTIONS
The pesticide should only be applied when the potential for drift to adjacent environmentally sensitive areas is minimal . May be applied to irrigated cotton fields.

RE-ENTRY STATEMENT
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, longsleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21CMixers/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-2 1C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

GENERAL USE PRECAUTIONS
Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.
PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.
CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
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IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

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5. Use 10 lbs of **ASPERGILLUS FLAVUS AF36** per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT
To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

Toxicology Data

Please refer to the following volumes:

LIST OF STUDIES IN THE CURRENT SUBMISSION

VOLUME NO. AND TITLE

Volume 2 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

Volume 3 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report.

Volume 4- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1.

Volume 5 - Honey bee Field Study of Aspergillus flavus AF36 in Cotton

Volume 7 - Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents Amendment No. 1 to MRID 43972402, Amendment No. 2 to MRID 43763404

Also please refer to MRID Number and Title of Previously submitted Volumes

43972403 Shelton, L. (1996) Acute Oral Toxicity in Rats:Aspergillus flavus isolate AF 36

43972402 Cotty, P. (1996) Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents With Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity Amendment No. 1 to MRID 43763404

43763404 Cotty, P. (1995) Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents With Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity

Aspergillus flavus AF-36 - Waiver request for Toxicology Data Requirements, in regard to petition proposing an exemption from the requirements of a tolerance for Sorbitol Octanoate for use in All Food Commodities .

Section M Guidelines: 152-10, 152-11, 152-13, 152-14, 152-15, 152-16, 152-17, 152-18, 152-19, 152-20, 152-21, 152-22, 152-23, 152-24, 152-26, 152-29

We request a waiver of all the toxicology data mentioned in 40 CFR 158.690 that pertains to the following guidelines*:

Kind of Data Required	Terrestrial Food Crop	Guideline Reference No.
Acute dermal toxicity	R	152-11
Primary eye irritation	R	152-13
Primary dermal irritation	R	152-14
Hypersensitivity study	CR	152-15
Hypersensitivity incidents	CR	152-16
Studies to detect genotoxicity	R	152-17
Immune response	R	152-18
90-day feeding	CR	152-20
90-day dermal	CR	152-21
90-day inhalation	CR	152-22
Teratogenicity	CR	152-23
Mammalian mutagenicity	CR	152-19
Immune response	CR	152-24
Chronic exposure	CR	152-26
Oncogenicity	CR	152-29

* Refer to volumes previously submitted for Toxicology data waiver requests and the rationale for requesting a waiver for each of the data requirements.

Non Target Organism Data and
Environmental Fate Data

Please refer to the following volumes:

LIST OF STUDIES IN THE CURRENT SUBMISSION

VOLUME NO. AND TITLE

Volume 6 Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P.. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

Aspergillus flavus AF36 - Waiver request for Nontarget organism, date and expression data requirements in regard to petition proposing an exemption from the requirements of a tolerance for Sorbitol Octanoate for use in All Food Commodities production.

Section M Guidelines: 154-6, 154-7, 154-8, 154-9, 154-10, 154-11

We request a waiver of all the nontarget organism, fate and expression data requirements mentioned in 40 CFR 158.690 that pertain to the following guidelines:*

Kind of Data Required	Terrestrial Food Crop	Guideline Reference No.
Avian acute oral	R	154-6
Avian dietary	R	154-7
Freshwater fish LC_{50}	R	154-8
Freshwater invertebrate LC_{50}	R	154-9
Nontarget plant studies	CR	154-10
Nontarget insect testing	CR	154-11

Rationale for Waiver Request of Non-Target Organism
and Environmental Expression Data Requirements

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material.throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

Efficacy Effects Data

Please refer to the following volume:

43763405 Cotty, P. Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data. USDA/ARS and IR-4.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, Arizona 85040-2933 (602) 438-0059	71693
Active Ingredient(s) and/or representative test compound(s): Aspergillus flavus AF-36	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158): Cotton fields	Product Name: Aspergillus flavus AF-36

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ X I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

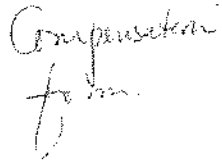
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
[signature]	8-8-02	LARRY ANTILLA - DIRECTOR

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date		EPA Reg No./File Symbol 71693	Page 1 of 4
Applicant's/Registrant's Name & Address	Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product AF-36	

Ingredient: Aspergillus flavus AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-10	Product Identity	43763401, 43990001	USDA/ARS	Own	
151-11	Manufacturing Process	43763401, 44597001, 44713701	AZ Cotton Research and Protection Council	Own	
151-12	Formulation of Unintentional Ingredients	43763401, 43990001	AZ Cotton Research and Protection Council	Own	
151-13	Analysis of Samples	43763402, 43972401, 44626101	AZ Cotton Research and Protection Council	Own	
151-15	Certification of Limits	43763402, 43972401, 44626101	AZ Cotton Research and Protection Council	Own	
151-16	Analytical Methods	43763402	AZ Cotton Research and Protection Council	Own	
151-17	Physical & Chemical Properties	43763402	AZ Cotton Research and Protection Council	Own	
152-10	Acute Oral	43972403	AZ Cotton Research and Protection Council	Own	
152-11	Acute Dermal	45307201	IR-4, Rutgers University	Exc 1	
152-12	Acute Inhalation	45307201	IR-4, Rutgers University	Exc 1	
152-13	Primary Eye Irritation	45307201	IR-4, Rutgers University	Exc 1	
152-14	Primary Dermal Irritation	45307201	IR-4, Rutgers University	Exc 1	
152-15	Hypersensitivity Incidents	43763404, 43972402	USDA/ARS	Own	
156A-2	Product Performance Data	43763405	USDA/ARS	Own	
154A-24	Honeybee Testing		AZ Cotton Research and Protection Council	Own	

Signature	Name and Title	Date
	Larry Autilla, Director	5-8-02

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Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date	EPA Reg No./File Symbol 71927-R	Page 2 of 4
Applicant's/Registrant's Name & Address: Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product: AF-36	

Ingredient: Aspergillus flavus AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			USDA/ARS	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			IR-4, Rutgers University	Exc 1	
			IR-4, Rutgers University	Exc 1	
			IR-4, Rutgers University	Exc 1	
			IR-4, Rutgers University	Exc 1	
			USDA/ARS	Own	
			USDA/ARS	Own	
			AZ Cotton Research and Protection Council	Own	

Signature: [signature]

Name and Title: Larry Antilla, Director

Date: 5-8-02

1 Waiver Requested

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date	EPA Reg No./File Symbol 71693	Page 3 of 4
Applicant's/Registrant's Name & Address: Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product: AF-36	

Ingredient: Aspergillus flavus AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17	Avian Inhalation		USDA/ARS	Own	
152-12	Acute Pulmonary Rat		USDA/ARS	Own	
154-16	Avian oral	45307201, 45307202	IR-4, Rutgers	Exc [1]	

Signature: [signature]

Name and Title: Larry Antilla, Director

Date: 8-8-02

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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

[1] Waiver Request

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

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Applicant's/Registrant's Name & Address: Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product: AF-36	

Ingredient: Aspergillus flavus isolate AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			USDA/ARS	Own	
			USDA/ARS	Own	
			IR-4, Rutgers	Exc	

Signature: [signature]

Name and Title: Larry Astilla, Director

Date: 5-8-02

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

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Meeting with IR-4, USDA (ARS)
Cotton Research Council and Growers (AZ)

November 7, 2002 @ 2 to 3:30 p.m.
Room 912A, Crystal Mall 2
1921 Jefferson Davis Highway, Crystal City, VA

Name	Organization	Phone #	email
Zig VAITUZIS	BPPD	703-308-8676	VAITUZIS.ZIGFRIDAS@EPA.GOV
Phil Wakelyn	NCC	202-745-7805	Pwakelyn@cotton.org
Peter Cotty	USDA, ARS	504-286-4391	pjcotty@srrc.ars.usda.gov
Larry Antilla	Az Cotton	(602)438-2085	lantilla@azcotton.com
Michael Braverman	IR-4	(732)932-8575 ext 610	braverman@aesop.rutgers.edu
JOHN KOUGH	BPPD	703-308-8267	KOUGH.JOHN@EPA.GOV
Shanaz Bacchus	BPPD	703-308-8097	bacchus.shanaz@epa.gov

Aflatoxin Research in Arizona

Aflatoxin, a by-product of several naturally occurring fungi, is recognized internationally as a serious food safety hazard. Aflatoxin is the biggest and most important mycotoxin problem affecting U.S. crops. It causes millions of dollars of crop losses to American agriculture each year. International food safety organizations have lowered acceptable aflatoxin levels in foods and feeds to near zero levels causing reduction in U.S. exports. The Arizona cotton industry as well as the corn, peanut, and tree nut industries in the U.S. have been struggling over the past 25-30 years to find an answer to aflatoxin, which represents a food safety issue as well as an economic problem. High aflatoxin levels severely limit grower's ability to sell cottonseed and other commodities and at certain levels the products cannot be shipped interstate. Development of procedures to produce food and feed free of aflatoxin requires a coordinated effort by both government and industry. The sale of aflatoxin-free cottonseed can represent the difference between profit and loss in an era of razor-thin margins for Arizona cotton producers.

While US food and feed producers and processors operate extensive management programs to reduce exposure to aflatoxin, the efficacy of this control strategy is limited. This is evidenced by the devasting occurance of aflatoxin in crops in some of the south, mid-south, and southwest in 1998, 1999, and this year as well as in corn in the mid-west this year. Much has been learned with the help of increased research funds provided by Congress since 1990 but the only thing being evaluated in the field that shows promise for controling this problem is the biocontrol strategy being evaluated in Arizona. This technology, using a biocontrol agent (AF 36) that does not produce aflatoxin and out competes the aflatoxin producing fungi, is very promising. EPA has granted a state wide 20,000-acre experimental use permit (EUP) for use of AF 36 in Arizona and for 2000-acres in Texas. USDA, ARS has issued a license to manufacture AF 36 and all the parties involved look forward to full Section 3 product registration.

Many cotton industry organizations (including Cotton Incorporated, the National Cotton Council, and the National Cottonseed Products Association) have contributed to this USDA project and the Arizona Cotton Research and Protection Council has initiated the development of a pilot manufacturing plant through the investment of 2.5 million dollars in grower funds. Similar research has been started in Texas for corn, cotton, and peanuts and for peanuts and tree nuts in other states. The completion of the Arizona research is vitally important to the use of this technology on other crops and in other parts of the US.

In FY 2000 Congress provided an additional $250,000 of permanent funds for this project. In FY 2001 and 2002 Congress provided $500,000 of new funds for this research and the FY 2003 budget continues theses funds. The Multi-Crop Aflatoxin Working Group, with representatives from corn, peanuts, cotton, and tree nuts, has been very supportive of this research which has applicability to other crops in other parts of the US.

The funding has been critical for development of this program (e.g., research of product viability under highly variable and stressful agronomic conditions; alternative dispersal systems; the development and analysis of automated control systems for incubation and drying of AF 36, which would significantly enhance the transfer of this technology to other commodity groups in other parts of the country).

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

10/28/02 04:07 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>, Larry Antilla <LAntilla@AZcotton.com>, Phil Wakelyn <pwakelyn@cotton.org>, Phil Hutton/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>, Larry Antilla <LAntilla@AZcotton.com>, Phil Wakelyn <pwakelyn@cotton.org>, Phil Hutton/DC/USEPA/US@EPA
Subject: FW: A. flavus AF36 meeting

Shanaz

Nov 7th is still good for us. I understand that Gail might not be available, so she can pass her comments on to you on agenda item #2 to have them available for the meeting.

To me the main agenda items are:

1. Industry needs for 2003- Alternative management techniques

2. Staus of the Section 3 review- Status of toxicology data review and overall projected completion date

3. EUP for 2003-how many acres for AZ and TX)

4. Label language

Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Phil Wakelyn [mailto:PWAKELYN@cotton.org]
Sent: Monday, October 28, 2002 8:57 AM
To: Bacchus.Shanaz@epamail.epa.gov
Cc: braverman@AESOP.RUTGERS.EDU; LAntilla@AZcotton.com; etsitty.carl@epamail.epa.gov; Hutton.Phil@epamail.epa.gov; Kough.John@epamail.epa.gov; Tomimatsu.Gail@epamail.epa.gov; Vaituzis.Zigfridas@epamail.epa.gov; pjcotty@srrc.ars.usda.gov
Subject: Re: A. flavus AF36 meeting

This date is exceptible as of now. I will work with Braverman and Cotty to get you an agenda.

>>> <Bacchus.Shanaz@epamail.epa.gov> 10/23/02 11:11AM >>>
Phil Hutton forwarded your proposed dates for a meeting with BPPD team members to me for set up. We can meet with you on Thursday, Nov 7, 2002
from 2 - 3:30 p.m. I was just told by your receptionist that you are in
Egypt and will return on Nov 1. If this meeting time is not good for

SYMBOL	SURNAME	DATE

you please let us know and we will reschednle I am copying Mike Braverman, Larry Antilla and Peter Schneeman to keep them in the loop. Please forward an agenda to me as soon as feasible.

If you have any questions, do not hesitate to email me.

Sincerely,
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Cotton Council AF36

Mtg 11/7/2002

Cost $50/ton/seed – '98, '99, 2000 – problems in other crops
Hi levels TX – corn a problem!
Midwest NE/IL
Multicrop Task Force (Aflatoxin) ⟷ corn
$ 100M/research.
hi in AZ seed cotton not analyzed for aflatox.
1500 ppb/75 ton
diff
Exemption] NH_3 not used in AZ
TX will not allow

[FDA review – method can be approved]

Decline acreage in industry –
Paloma Council. 5000

Tox 1 Pulmonary Rat Tween 80.
2 " " Interim Rpt – physiol saline
(range finding) [10^{8} – 10^{9} no effect –
3 Completion of interim report. did 10^{8}]

Health Effects.
4 Hypersensitivity (letters from growers)
lack of hypersensit.

Env Avian Inhal
Honey bees.
Non tgt – Plovers – Fed Register.

Need for Data waivers.
→ GLP Compliance – not legal – Sound but doesn't meet GLP.

initial protocol — asked why not intratracheal

H_2O · TX. | Document H_2O org –

Tech.

Daphnia –

→ Public Interest Finding.

3" vegetation. nesting habitats of birds.

Label

ground ⟷

Acreages.

↓

{ 40,000 A in AZ ⟷
5,000 A / TX.
Label amendment TX }

22000 A /

Technical adjustment acreages.

3 yrs ⟷

→ Annual report [Summarize.
3 yrs – (700 fields)
< 2% fields treated 2 successive yrs)]

Marylyn Lutke (FDA.)

AF-36 Section 3 Registration Meeting Agenda

November 7, 2002

BPPD, USDA, Arizona Cotton Research and Protection Council, National Cotton Council, IR-4

1. Industry needs for 2003- Alternative management techniques

2. Status of the Section 3 review- Status of toxicology data review and overall projected completion date

3. EUP for 2003- (how many acres for AZ and TX)

4. Label language

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

MAY 24 2002

SUBJECT: Response to Comments by Dr. David Wilson, Professor of Plant Pathology, University of Georgia on the EUP Extension for AF36 to Include Texas Cotton.

TO: Shanaz Bacchus
Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

FROM: Carl Etsitty, M.S., Microbiologist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

THROUGH: John L. Kough, Senior Scientist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

ACTION REQUESTED: To address the comments received about the use of the atoxigenic strain of *Aspergillus flavus* in Texas cotton.

SUMMARY OF COMMENTS: Dr. David Wilson, professor of plant pathology at the University of Georgia made a number of comments in response to an FR announcement concerning an extension of an experimental use permit (EUP) for treating cotton with a competitive fungal agent to reduce aflatoxin contamination. Dr. Wilson's concerns cover three areas: uniform standards in expression of the aflatoxin levels found in the crop; the practical significance of the proposed treatment method in reducing aflatoxin contamination; and the significance of host stress in the expression of pathogenicity by *Aspergillus flavus*.

RESPONSE TO COMMENTS: Uniform standards are an essential feature in communicating scientific information as the commenter noted. In this instance, the commenter referred to the mixing of units used to measure aflatoxin contamination. In one place the registrant referred to aflatoxin levels in micrograms per gram of cottonseed, whereas the commenter indicated that aflatoxin contamination is typically expressed in micrograms per kilogram of cottonseed, a thousand fold lower level. While it is important to maintain the proper units of measure there is no indication that the company was in error or misrepresenting the aflatoxin values they obtained. EPA is careful to pay close scrutiny to the units of measure in data they review and the implications made from the stated values.

The second point made was regarding the efficacy of biological control measures to reduce the level of aflatoxin contamination in commercial crops. The commenter doubts that the demonstrated or implied reductions in aflatoxin levels presented by the company will ever result in an improved marketability of the treated crop. The efficacy of pesticidal products are a concern of EPA and, for products which control aflatoxin contamination, there is a specific requirement that the company present data to confirm their claim to control a public health threat. It is important to note that no matter what the EPA decides on the matter of permanent tolerance for the proposed product, the FDA standards for acceptable levels of aflatoxin in various foods (e.g., cottonseed meal, corn, peanuts) will not be changed. All the commodities, treated or otherwise still need to be under the published FDA standards to enter the food or feed supply.

The efficacy of the proposed treatment will need to be judged in terms of reduced aflatoxin contamination. This reduction does not, however, imply that the entire treated crop needs to meet the FDA aflatoxin standard. If a higher percentage of the treated commodity meets the standard or if the aflatoxin contamination in the region is lowered as a result of the treatment, that may indicate efficacy. It will be for the growers to decide if the reduced aflatoxin contamination is worth the treatment costs. This is a difficult question to address since *Aspergillus flavus* colonization with subsequent aflatoxin contamination is a sporadic event even in commodities where it is a chronic problem as the case with Arizona cottonseed.

The third point is that the atoxigenic fungus *Aspergillus flavus* AF36 must be tested on stressed or immunosuppressed species to detect any pathogenic potential in plants, insects or mammals. EPA recognizes that microbial agents such as the atoxigenic fungus *Aspergillus flavus* AF36 have unique hazards to examine compared to chemical pesticides. EPA has developed a series of guidelines [OPPTS 885 Series] specifically to address the issue of potential pathogenicity to mammals and other non-target species. These guidelines are designed to address the normal immune response to microbial exposure which includes non-self/foreign recognition and an eventual a response or clearance by the immune system over time. Any microbe, when given the opportunity, will probably colonize a host without normal immune resistance. This colonization may lead to proliferation, infection and even pathogenicity. EPA is examining new methods that may address the potential of a microbe to infect stressed or immunocompromised hosts. In the interim, special measures have been included in the experimental treatments with the atoxigenic fungus *Aspergillus flavus* AF36. These measures will greatly reduce any fungal exposure outside of the designed experimental use area. The experimental plan requires extensive data collection to examine the fate and persistence of the atoxigenic fungus *Aspergillus flavus* AF36 as a component of the local fungal

population.

Lastly, as an important to note, *Aspergillus flavus* is a normal component of the environment; exposure to this microbe is inevitable unless extraordinary precautions are taken. Given the ubiquitous nature, precautions associated with the experimental use to avoid unnecessary exposure, data indicating no harm to test rodent species by oral ingestion of the atoxigenic fungus *Aspergillus flavus* AF36 as well as the current FDA monitoring of aflatoxin levels in cottonseed, there is a reasonable certainty of no harm resulting from the use of the atoxigenic fungus *Aspergillus flavus* AF36 under the current EUP.

Confidential Statement of Formula may be entitled to confidential treatment

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Establish and adhere to a 400 foot buffer zone for all AF36 treatments with respect to all schools, day care centers, hospitals, nursing homes, health care and other treatment centers where immune compromised individuals may be found. In Texas, do not apply within 20 yards from the edge of a stream channel and select sites where vegetation around the cotton fields is at least 3 inches.

AGRICULTURAL USE DIRECTIONS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

RE-ENTRY STATEMENT

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21CMixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of pro-duct needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers: Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

EXPERIMENTAL USE PESTICIDE

EXPERIMENTAL USE ONLY - NOT FOR SALE TO ANY PERSON OTHER THAN PARTICIPANT OR COOPERATOR OF THE EPA - APPROVED EXPERIMENTAL USE PROGRAM THIS LABEL MUST BE IN THE POSSESSION OF THE USER AT THE TIME OF APPLICATION

FOR USE ONLY AT AN APPLICATION SITE OF A COOPERATOR AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE EXPERIMENTAL PROGRAM -READ SAFETY DIRECTIONS BEFORE OPENING

ASPERGILLUS FLAVUS AF36

FOR REOUCED AFLATOXIN CONTAMINATION OF COTTONSEED

ASPERGILLUS FLAVUS AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied just prior to first bloom, **ASPERGILLUS FLAVUS AF36** competes with strains of Aspergillus flavus that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop. Thus, **ASPERGILLUS FLAVUS AF36** reduces the quantity of aflatoxin contaminating the crop.

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert Ingredients:	0%
Total:	100%

EUP number 69224-EUP-1

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224-EUP-1
EPA Establishment Number 71693-AZ-001

USDA/ARS Southern Regional Research Center
New Orleans, LA 70179

NET CONTENTS: 50 lbs, 1000-3000 lbs

GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply in combination with fertilizers, insecticides, or fungicides.

ACCEPTED

for shipment and use of product for experimental purposes under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.

Permit No. 69224-EUP-1

Issued on 01/2/02

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For application to cotton to control aflatoxin producing strains of *Aspergillus flavus*.

ASPERGILLUS FLAVUS AF36 has been shown to reduce aflatoxin contamination of cottonseed by competitively excluding aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

DIRECTIONS FOR USE

1. **ASPERGILLUS FLAVUS AF36** may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of **ASPERGILLUS FLAVUS AF36** under the canopy and to minimize delivery of **ASPERGILLUS FLAVUS AF36** to furrows.
3. **ASPERGILLUS FLAVUS AF36** has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of **ASPERGILLUS FLAVUS AF36.**
5. Use 10 lbs of **ASPERGILLUS FLAVUS AF36** per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. If applying aerially, apply when wind speed is 10 mph or less. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

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Protocol Review

Interregional Research Project No. 4
Center for Minor Crop Pest Management

TO: Shanaz Bacchus

FROM: W. Biehn (IR-4)

DATE: 10/22/01

NUMBER OF PAGES INCLUDING THIS COVERSHEET: 8

RE: AF36 Avian Inhalation Study

In the attached memo, it was agreed to dose birds at 105 conidia/ml for 5 days. See Test Material Dosage Section

Then for a 50 gram bird ~~we~~ we would dose 1000 spores/day/bird

Please confirm this is correct

(MPCA=10^5) X 0.2 ml/kg BW X .05 kg + weight of bird

I need a Reply This Week

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM JUL 10 2001

SUBJECT: Review of Additional Material for *A. flavus* AF36 on Cotton - MRID 453072-02

TO: Shanaz Bacchus, Regulatory Action Leader
Biopesticides and Pollution Prevention Division (7511C)

FROM: Gail S. Tomimatsu, Ph. D., Plant Pathologist, G. Vaituzis 6/29/01
Biopesticides and Pollution Prevention Division (7511C)

THROUGH: Zigfridas Vaituzis, Ph. D., Senior Scientist Z. Vaituzis 6/29/01
Biopesticides and Pollution Prevention Division (7511C)

REGULATORY BACKGROUND and CONCLUSIONS

In 1999, BPPD determined that submitted materials and public information regarding the *A. flavus* biology and ecology, were sufficient to justify experimental applications of the MPCA (atoxigenic *A. flavus* Strain AF36) on 20,000 acres of cotton to reduce natural populations of toxigenic (aflatoxin-producing) *A. flavus*. Nontarget avian (oral and pulmonary routes of exposure) and honeybee toxicity/pathogenicity testing were required for full registration on cotton grown in Arizona. As a further condition of the EUP, data from air monitoring studies of *Aspergillus flavus* spore levels produced in treated and non-treated control fields were required during testing, especially during July through October, when spore loads are expected to be at peak levels.

Dr. Peter Cotty, through IR-4 has submitted the requested studies of *Aspergillus flavus* spore levels produced in treated and non-treated control fields in the MRID # 453072-02. A formal DER is unnecessary for the study, as no specific OPPTS Guidelines were addressed and results help establish a "baseline" for populations of *A. flavus* in cotton fields. Furthermore, much of the study will be published in a peer-reviewed journal. Accordingly, the study is rated supplemental and will be kept on file for reference as needed.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 10 2001

MEMORANDUM

SUBJECT: Review of Protocol for Testing the Toxicity/Pathogenicity of the MPCA, *Aspergillus flavus* Strain AF36 (Chemical No.:006456) to Avian Species: DP Barcode:D274694; Case No:03976; Submission:S596777; ID #: 069224-EUP-001

TO: Shanaz Bacchus, Regulatory Action Leader
Biopesticides and Pollution Prevention Division (7511C)

FROM: (per) Gail S. Tomimatsu, Ph. D., Plant Pathologist, 6/29/01
Biopesticides and Pollution Prevention Division (7511C)

THROUGH: Zigfridas Vaituzis, Ph. D., Senior Scientist 6/29/01
Biopesticides and Pollution Prevention Division (7511C)

ACTION REQUESTED

A draft protocol for evaluation of avian pulmonary risks to the MPCA, *Aspergillus flavus* Strain AF36 was submitted for review and comment prior to testing at a European contracting facility, Huntingdon Life Sciences, Ltd., Wooley Road, Alconbury, Huntingdon, Cambridgeshire PE28 4HS, ENGLAND. According to the submission, the study will be conducted in compliance with the principles of Good Laboratory Practice Standards as set forth in: UK Good Laboratory Practice Regulations 1999 (Statutory Instrument No. 3106), the OECD Principles of Good Laboratory Practice (rev. in 1997), ENV/MC/CHEM(98)17, and the EC Commission Directive 1999/11/EC of March 8, 1999 (Official Journal No. L. 77/8).

REGULATORY BACKGROUND

In 1999, BPPD determined that submitted materials and public information regarding the *A. flavus* biology and ecology were sufficient to justify experimental applications of the MPCA (atoxigenic *A. flavus* Strain AF36) on 20,000 acres of cotton to reduce natural populations of toxigenic (aflatoxin-producing) *A. flavus*. Avian (oral and pulmonary routes of exposure) and honeybee toxicity/pathogenicity testing were required for full registration on cotton grown in

Arizona. Further, it was recommended that avian pulmonary pathogenicity tests be performed since the inhalation route is the most likely pathway for Aspergillosis infection in avian species. The current OPPTS Guideline 885.4100 recommends either of two approaches for dosing test birds: tracheal instillation and aerosol inhalation.

SPECIFIC COMMENTS TO AVIAN ACUTE PULMONARY PATHOGENESIS TESTING

Method of Dose Administration

According to the draft protocol, test doses will be administered by direct intratracheal instillation (IT). The preferred route of administering MPCAs for pulmonary exposures involve inhalation administrations, since these represent a more accurate simulation of field exposures. Other studies (EPA, 1990) have shown that IT instillation results in a particle size deposition in the respiratory tract that is very different from that of aerosol inhalation. For example, in a comparison study of aerosol exposures and IT instillations of microspheres (within the range of particles sizes from Arizona cotton fields; Bock and Cotty, submitted 2001) and microorganisms on bobwhite quail chicks, there were markedly higher frequencies of the microparticles (or microorganisms) distributed in tissues other than the nasal/tracheal for the instillation than with the aerosol inhalation administration. Consequently, the IT instillation method of dosing does not appear to present a "worst-case scenario" when compared to the aerosol-inhalation method of dosing. Also, delivery of the microorganisms via the instillation approach may also result in expulsion of the dosing solution, thereby contaminating bird feathers, or even the handler.

A justification for using the direct intratracheal instillation route of administration instead of the preferred inhalation route should accompany the study.

Test Material Dosage

The maximum daily dose of 10^5 conidia/ml is preferable to the previously agreed dosage of 5×10^4 *Aspergillus flavus* spores/ml as discussed via telephone agreement between Dr. William Biehn, IR-4 and Dr. Doug Gurian-Sherman, U.S. EPA on September 21, 2000. This dosage is apparently based on the maximum number of spores recovered daily from air samplers (400 to 450 conidia m^3) in, or proximal to cotton fields during May 1997 to March 1999 (Bock and Cotty, 2001.; MRID 453072-02). In the Addendum to the Protocol, the author (author unknown) specifies that the concentration of *Aspergillus flavus* AF36 should be 10^5 conidia per ml. Furthermore, the daily dosing concentration should be verified by dilution plate technique (after 48 hours of incubation) each of the 5 days that the birds are dosed, since the protocol specifies that fresh dosing solutions be prepared daily.

Preparation of Dosing Solutions and Treatments

The vehicle (p. 5, Item 3.2- to be confirmed) used to deliver the *A. flavus* dosages should be used as the basis of a negative control (p. 7, Item 5.1). The protocol specifies that the

infectivity control group be treated with inactivated *A. flavus* AF36; the inactivated fungal inoculum should be prepared by mixing the fungal suspension with formalin or another chemical (perhaps 0.05% sodium hypochlorite) that has been shown to inhibit conidial germination or mycelial growth, without compromising conidial integrity. Following suspension, the inactivated fungus should be washed a minimum of three times and resuspended in sterile buffered saline or the "vehicle" (sterile) for inoculation. Conidial populations should also be estimated with a hemacytometer or other suitable counting chamber.

Observations (Acclimation, During Test, Post-Dosing, Post-*mortem*)

The protocols as described are acceptable. The contracting laboratory may also wish to consider including any evidence of respiratory tract involvement and involvement at distant sites including liver, kidney, spleen, cerebrospinal system, gastrointestinal system in their necropsy report(s). Assessments of histopathological findings, lesions noted and MPCA tissue isolations should be included in the final study report. Complete methodology for histopathological preparations, MPCA isolations and microbiological quantification procedures need inclusion in the final report also.

The submitted protocol is very similar to procedures established in OPPTS Guideline 885.4100, Avian Inhalation Test, Tier I, test protocols which have not been evaluated in the laboratory. Accordingly, we find the submitted protocol scientifically sound. The final report should also include diet and water analyses, as well as information regarding the intensity of the lights (lux) during the 14-hr/10 hr darkness photoperiod.

Literature Cited:

1. Bock, C.H. and P.J. Cotty. 2001. Seasonal changes in the quantities of *Aspergillus flavus* and other propagules in the air over Arizona cotton fields. Phytopathology 91 (?) : in press.

2. MRID 453072-02: "Aspergillus flavus isolate AF36 Nontarget Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of *A. flavus*".) Project I.D. Number IR-4 PR No. 52B. (No EPA Data Evaluation Report prepared).

United States
Environmental Protection
Agency

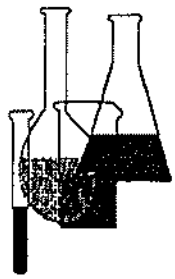
Prevention, Pesticides
and Toxic Substances
(7101)

EPA 712-C-96-330
February 1996

EPA

Microbial Pesticide Test Guidelines

OPPTS 885.4100
Avian Inhalation Test, Tier I



OPPTS 885.4100 Avian inhalation test, Tier I.

(a) Scope—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 154A–17. The Agency recognizes that this test protocol has not yet been evaluated in the laboratory. An inhalation exposure may be acceptable in lieu of instillation and, for some microorganisms, the Agency may accept a request for waiver of this test with appropriate justification. It would be advisable to contact the Agency before performing the respiratory testing.

(b) **Test standards.** Data on avian respiratory pathogenicity of microbial pest control agents (MPCAs) must be derived from tests which satisfy the purposes of the general test standards in OPPTS 885.0001, and all the following test standards:

(1) **Test substance.** The actual form of the material to be used as the test substance is described in OPPTS 885.4000. In addition, any substances used to enhance virulence or toxicity should be tested along with the test substance.

(2) **Species.** Testing shall be performed on one avian species (preferably bobwhite quail). Other species may be used but a justification must be supplied based on increased susceptibility to the MPCA or ecological considerations which preclude the use of recommended species.

(3) **Age.** Birds used in this test should be from 14 to 28 days old at the beginning of the testing period. Within a given test, all birds shall be as close to the same age as possible.

(4) **Controls.** (i) A negative, nondosed control group is required.

(ii) A concurrent control group is required and shall be treated with the pure active ingredient that has been inactivated in such a way as to preserve cellular integrity.

(iii) After dosing, two untreated contact control birds are required and shall be placed in with the treatment group receiving the maximum hazard dosage.

(5) **Number of birds per dosage level.** Each treatment and control group shall contain at least 10 birds. When there is only one treatment group at least 30 birds shall be tested at that treatment level.

(6) **Route of exposure.** The test material should be administered by intranasal or intratracheal instillation. Depending on the physical properties of the agent being tested, an alternate route, such as use of an aerosol,

90

This is an ACCEPTED submission.

One copy of the PPC diagnosis and one copy of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a PARTIALLY ACCEPTED / COMPLETELY REJECTED submission.

A copy of the PPC diagnosis and the annotated bibliography are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

DEC 18 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

INTERREGIONAL RESEARCH PROJECT NO. 4
NJ AGRICULTURAL EXPERIMENT STA
P.O. BOX 231
NEW BRUNSWICK, NJ 089030231

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/11/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

447137-00

12-28-98
ISPPD

Interregional Research Project No. 4
Center for Minor Crop Pest Management

DEC 10 1998

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460-0001

Subject: Aspergillus flavus AF36/Cotton (AZ only)
Petition Amendment PP8E5001
EPA Company No. 71693
Amended Manufacturing Process and Additional Non-Target Organism and Environmental Safety Information

Response to: EPA Letter of September 16, 1998 Entitled
Preregistration Meeting on Aspergillus flavus AF36
on Cotton in Arizona - Additional Response Items

Dear Dr. Andersen:

This is in regard to EPA's letter of 16 September 1998 (see attachment). Enclosed are our responses to items 3,7,8,9 and 11 of EPA's letter as well as items (a), (b) and (c) on page 2 of EPA's letter.

Regarding item 3 of EPA's letter, we agree that the word elimination is inappropriate and will in the future only refer to it as an aflatoxin reduction program.

Regarding items 7,8 and 11, enclosed please find additional non-target-organism and environmental safety information as well as a revised manufacturing process.

List of Studies Submitted in Support of Proposed Exemption from the Requirement of a Tolerance for Aspergillus flavus isolate AF36.

continued . . . . . .

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Dr. Janet Andersen (con't)

Volume No. and Title

Volume 1 - Aspergillus flavus isolate AF36 - Non-target Organism and Environmental Safety Information - Additional Rationale for Waivers - Addendum to Volume 6 of 7 Submitted to EPA on 7/1/98.

Admin.

Volume 2 - Aspergillus flavus isolate AF36 - Amended Manufacturing process Amendment No. 3 to MRID No. 43763401.

44713701

Regarding item 9 of EPA's letter, the labels submitted to EPA on 7/1/98 require applicators and other handlers to wear the following personal protective equipment: coveralls, long sleeved shirt and long pants, waterproof gloves, shoes plus socks and a dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C.

Regarding EPA's comment under item (a) on page 2, sterile techniques will be maintained and the manufacturing staff will be trained to maintain these techniques.

Regarding EPA's comment under item (b) on page 2, pillow cases containing seeds are only used for drying in the small scale lab production and will not be used for drying the seed for either the proposed Experimental Use Permit or the Section 3 Registration.

Regarding items (a), (b) and (c) on page 2 of EPA's letter of 9/16/98, please see attached report entitled "Aspergillus flavus isolate AF36 - Amended Manufacturing Process".

Regarding item (c), exhaust air will be passed through a HEPA filter that will prevent release of contaminants. Regarding item (c), product integrity (quality) will be monitored by the quality assurance steps outlined on pages 9 and 10 of MRID #44626101.

Sincerely,

William L Biehn

William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:js
Enclosure

cc: Peter Cotty, USDA/ARS (w/encl)
Larry Antilla, ACRPC (w/encl)
Phil Wakelyn, National Cotton Council (w/o encl)
Jane Robens, USDA/ARS (w/o encl)
Phil Hutton, EPA (w/o encl)

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447137-00

Interregional Research Project No. 4
Center for Minor Crop Pest Management

DEC 10 1998

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460-0001

Subject: Aspergillus flavus AF36/Cotton (AZ only)
Petition Amendment PP8E5001
EPA Company No. 71693
Amended Manufacturing Process and Additional Non-Target Organism and Environmental Safety Information

Response to: EPA Letter of September 16, 1998 Entitled Preregistration Meeting on Aspergillus flavus AF36 on Cotton in Arizona - Additional Response Items

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This is in regard to EPA's letter of 16 September 1998 (see attachment). Enclosed are our responses to items 3,7,8,9 and 11 of EPA's letter as well as items (a), (b) and (c) on page 2 of EPA's letter.

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List of Studies Submitted in Support of Proposed Exemption from the Requirement of a Tolerance for Aspergillus flavus isolate AF36.

continued .....

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY

Dr. Janet Andersen (con't)

Volume No. and Title

Volume 1 - Aspergillus flavus isolate AF36 - Non-target Organism and Environmental Safety Information - Additional Rationale for Waivers - Addendum to Volume 6 of 7 Submitted to EPA on 7/1/98.

Admin.

Volume 2 - Aspergillus flavus isolate AF36 - Amended Manufacturing process Amendment No. 3 to MRID No. 43763401.

44713701

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Regarding items (a), (b) and (c) on page 2 of EPA's letter of 9/16/98, please see attached report entitled "Aspergillus flavus isolate AF36 - Amended Manufacturing Process".

Regarding item (c), exhaust air will be passed through a HEPA filter that will prevent release of contaminants. Regarding item (c), product integrity (quality) will be monitored by the quality assurance steps outlined on pages 9 and 10 of MRID #44626101.

Sincerely,

William L Biehn

William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:js
Enclosure

cc: Peter Cotty, USDA/ARS (w/encl)
Larry Antilla, ACRPC (w/encl)
Phil Wakelyn, National Cotton Council (w/o encl)
Jane Robens, USDA/ARS (w/o encl)
Phil Hutton, EPA (w/o encl)

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ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
2403 West Huntington, Suite 101,
Tempe, Arizona 85282-3166
(602) 438-0059
(602) 438-0407 - Fax

June 26, 1998

Dr. Janet Anderson
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (APPL)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460-0001

Subject : Aspergillus flavus AF 36
Arizona Cotton Research and Protection Council Application
EPA Company No.: 71693

Dear Dr. Anderson:

Enclosed please find our Application for Pesticide Registration for the above subject product. Enclosed also are:

1. product chemistry information,
2. proposed label (five copies);
3. confidential statement of formula;
4. certification with respect to citation of data statement, etc

In support of this application, please refer to the following petition entitled:
"Aspergillus flavus isolate AF 36 / Tolerance Exemption in or on Cotton".

The above petition was submitted by IR-4 on behalf of the USDA and the Arizona Cotton Research and Protection Council.

As per PR Notice 88-4, the registration of the above use is exempt from fees.

Sincerely,

Larry Antilla
ACRPC,
Staff Director

win\Aflatoxin\Use permit

TABLE OF CONTENTS

United States Department of Agriculture
Agricultural Research Service
Mid South Area Southern Regional Research Center
1100 Robert E. Lee Boulevard
P. O. Box 19687
New Orleans, Louisiana
70179-0687

June 18, 1998

Dr. Janet Anderson
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs - 7504C
U. S. Environmental Protection Agency
401 M. Street (SW), Washington, DC 20460-0001

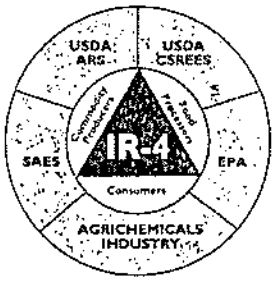
RE: *ASPERGILLUS FLAVUS* AF36

Dear Dr. Anderson:

This letter authorizes the Environmental Protection Agency to refer to the USDA/ARS Southern Regional Research Center data on *Aspergillus flavus* when considering the application for registration of *Aspergillus flavus* AF36 submitted by the Arizona Cotton Research and Protection Council.

Sincerely,

Peter J. Cotty
Research Plant Pathologist



Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division (7511W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460

JUN 25 1998

RE: Aspergillus flavus isolate AF36 Tolerance
Exemption for Cotton

Dear Dr. Andersen:

The IR-4 Project authorizes the EPA to review the above subject petition which was submitted to EPA on 6/25/98 in support of the application for registration of Aspergillus flavus AF36 that is being submitted by Larry Antilla of the Arizona Cotton Research and Protection Council.

Sincerely,

William L Biehn

William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:js

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 246110

Application for Pesticide - Section I

1. Company/Product Number: 71693
2. EPA Product Manager: S. Bacchus
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): ASPERGILLUS FLAVUS AF36
PM#:
5. Name and Address of Applicant *(Include ZIP Code)*:
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166
[ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [X] Other (Specify) Bulk Bags
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container
4. Size(s) Retail Container: Paper Bag: 50 lbs. Bulk Bags: 1000-3000 lb.
5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Larry Antilla	Staff Director	602-438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Larry Antilla
3. Title: Staff Director
4. Typed Name: Larry Antilla
5. Date: 6-26-98

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (Original) Yellow - Applicant Copy

Form Approved. OMB No. 2070-0060. Approval expires 5/98

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE 1 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693

3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED:

7. NAME OF STUDY	SOURCE OF STUDY: a. APPLICANT CONDUCTED STUDY (mark "X")	b. OBTAINED FROM EPA (mark "X")	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	f. ACCESSION NUMBER (if known)
Aspergillus flavus isolate AF36 - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.			USDA/ARS, Southern Regional Research Center, 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43763401
Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43763402

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? ☐ YES ☐ NO

EPA Form 8570-20 (Rev. 5-95)

APPLICANT-RETAIN THE LAST COPY

EPA COPY

Form Approved. OMB No. 2070-0060. Approval expires 5/98

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

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1. PAGE 2 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693

3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME Aspergillus flavus AF36

5. PRODUCT MANAGER Shanaz Bacchus

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Aspergillus flavus isolate AF36 - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients - Amendment No. 1 to MRID No. 43763401.			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43990001
Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits - Amendment No. 1 to MRID No. 43763402.			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43972401

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? ☐ YES ☐ NO

EPA Form 8570-20 (Rev. 1-91) APPLICANT-RETAIN THE LAST COPY EPA COPY

Form Approved. OMB No. 2070-0060. Approval expires 5/98

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

[See instructions on the back of the last page before completing.]

1. PAGE 3 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693

3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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Aspergillus flavus isolate AF36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID No. 43763401.	X					Submitted 6/25/98
Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits. Amendment No. 2 to MRID No. 43763402.	X					Submitted 6/25/98

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? ☒ YES ☐ NO

EPA Form 8570-20 (Rev. 1-91)

APPLICANT-RETAIN THE LAST COPY

Form Approved. OMB No. 2070-0060. Approval expires 5/90

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE 4 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693

3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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7. NAME OF STUDY	SOURCE OF STUDY					8. ACCESSION NUMBER (if known)
	a. APPLICANT CONDUCTED STUDY (mark "X")	b. OBTAINED FROM EPA (mark "X")	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	
Aspergillus flavus isolate AF36 - Safety Data in Support of Petition proposing a Temporary Exemption from the Requirement of a tolerance for Aspergillus flavus for use in cotton.			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43763403
Acute Oral Toxicity Study in Rats			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43972403
Aspergillus flavus isolate AF36 - Hypersensitivity Incidents with Microbial Pest Control Agents - Statement of Finding of No Hypersensitivity.			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43763404

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? ☐ YES ☐ NO

EPA Form 8570-20 (Rev. 1-91) APPLICANT-RETAIN THE LAST COPY EPA COPY

Form Approved. OMB No. 2070-0060. Approval expires 5/98

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

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1. PAGE 5 OF 6

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Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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	a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	
Aspergillus flavus isolate AF36 - Hypersensitivity Incidents with			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43972402
Microbial Pest Contrl Agents - Statement of Finding of No Hypersensitivity - Amendment No. 1 to MRID No. 43763404.						
Aspergillus flavus isolate AF36 - Safety Information.			IR-4 Project, Technology Centre of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390			Submitted 6/25/98
Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information			IR-4 Project, Technology Centre of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390			Submitted 6/25/98

If you marked "X" in this column, do you wish your name placed on the Data Submitters List? ☐ YES ☐ NO

EPA Form 8570-20 (Rev. 1-91) APPLICANT-RETAIN THE LAST COPY EPA COPY

Form Approved. OMB No. 2070-0060. Approval expires 5/98

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

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1. PAGE 6 OF 6

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3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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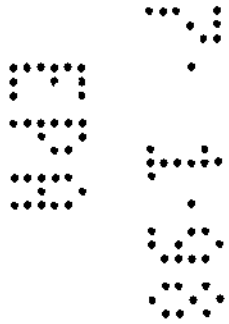
7. NAME OF STUDY	SOURCE OF STUDY					8. ACCESSION NUMBER *(if known)*
	a. APPLICANT CONDUCTED STUDY *(mark 'X')*	b. OBTAINED FROM EPA *(mark 'X')*	c. OBTAINED FROM ANOTHER FIRM OR SOURCE *(give name and address)*	d. OBTAINED FROM PUBLIC LITERATURE *(give reference)*	e. OTHER *(explain)*	
Aspergillus flavus isolate AF36 - Plant			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			Submitted 6/25/98
Studies - Request for Waiving of the Requirement for Testing.						
Aspergillus flavus isolate AF36 - Product			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43763405
Performance Data.						
	If you marked "X" in this column, do you wish your name placed on the Data Submitters List?			☐ YES ☐ NO		

EPA Form 3570-20 (Rev. 1-91) APPLICANT-RETAIN THE LAST COPY

219

CONFIDENTIAL STATEMENT
OF FORMULA FOR END USE PRODUCT



Confidential Statement of Formula may be entitled to confidential treatment

Product Chemistry Data (Aspergillus flavus AF36)

Refer to the following MRID Numbers:

43763401 (submitted to EPA on 8/9/95)
43763402 (submitted to EPA on 8/9/95)
43972401 (submitted to EPA on 4/3/96)
43990001 (submitted to EPA on 4/24/96)

Please also refer to the following studies:

Aspergillus flavus isolate AF36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID No. 43763401.

Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical methods for Certified Limits. Amendment No. 2 to MRID No. 43763402.

The above two studies were submitted to EPA on 6/25/98 as Volume 3 and 4 of a petition proposing an exemption from the requirement of a tolerance for Aspergillus flavus isolate AF36 use in cotton production.

PROPOSED SAMPLE LABEL

ASPERGILLUS FLAVUS AF36

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert Ingredients:	0%
Total:	100%

EPA Reg. No. 71693-

EPA Est. No. 71693-AZ-001

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive #101
Tempe, AZ 85282-3166

Net Weight 50 lbs., 1000 - 3000 lbs.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

COTTON (ARIZONA ONLY)

ASPERGILLUS FLAVUS AF36 is not for sale and is only for use in an area-wide program to reduce aflatoxin contamination of cottonseed conducted in cooperation with the Arizona Cotton Research and Protection Council. ASPERGILLUS FLAVUS AF36 is for application to cotton to reduce the aflatoxin producing potential of fungi resident in agricultural fields. ASPERGILLUS FLAVUS AF 36 is a strain of Aspergillus flavus that occurs naturally on the cotton crop. When applied just prior to bloom, ASPERGILLUS FLAVUS AF36 has been shown to competitively exclude aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

DIRECTIONS FOR USE

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.

2. Best results will be achieved when the applicator is adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.

3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.

4. For best results, the crop should be furrow irrigated within seven days after application of ASPERGILLUS FLAVUS AF36.

5. Use 10 lbs. of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficiency. To avoid drift, do not apply under windy conditions.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION - Avoid breathing dust. Avoid contact with eyes and skin. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

USE DIRECTIONS

PERSONAL PROTECTIVE EQUIPMENT
APPPLICATORS AND OTHER HANDLERS MUST WEAR:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50°C (122°F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.)-Completely empty bag into application equipment. Then dispose of empty bad in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers - Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing or other human/animal uses.

WARRANTY: User assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith. In no event shall the manufacturer be liable for special, incidental or consequential damages.

PROPOSED SAMPLE LABEL

ASPERGILLUS FLAVUS AF36

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert Ingredients:	0%
Total:	100%

EPA Reg. No. 71693-

EPA Est. No. 71693-AZ-001

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive #101
Tempe, AZ 85282-3166

Net Weight 50 lbs., 1000 - 3000 lbs.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is:

- o Coveralls
- o Long sleeved shirt and long pants
- o Waterproof gloves
- o Shoes plus socks
- o Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

COTTON (ARIZONA ONLY)

ASPERGILLUS FLAVUS AF36 is not for sale and is only for use in an area-wide program to reduce aflatoxin contamination of cottonseed conducted in cooperation with the Arizona Cotton Research and Protection Council. ASPERGILLUS FLAVUS AF36 is for application to cotton to reduce the aflatoxin producing potential of fungi resident in agricultural fields. ASPERGILLUS FLAVUS AF 36 is a strain of Aspergillus flavus that occurs naturally on the cotton crop. When applied just prior to bloom, ASPERGILLUS FLAVUS AF36 has been shown to competitively exclude aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

DIRECTIONS FOR USE

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.

2. Best results will be achieved when the applicator is adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.

3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.

4. For best results, the crop should be furrow irrigated within seven days after application of ASPERGILLUS FLAVUS AF36.

5. Use 10 lbs. of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficiency. To avoid drift, do not apply under windy conditions.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION - Avoid breathing dust. Avoid contact with eyes and skin. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

USE DIRECTIONS

PERSONAL PROTECTIVE EQUIPMENT
APPPLICATORS AND OTHER HANDLERS MUST WEAR:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50°C (122°F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.)-Completely empty bag into application equipment. Then dispose of empty bad in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers - Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing or other human/animal uses.

WARRANTY: User assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith. In no event shall the manufacturer be liable for special, incidental or consequential damages.

PROPOSED SAMPLE LABEL

ASPERGILLUS FLAVUS AF36

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert Ingredients:	0%
Total:	100%

EPA Reg. No. 71693-

EPA Est. No. 71693-AZ-001

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive #101
Tempe, AZ 85282-3166

Net Weight 50 lbs., 1000 - 3000 lbs.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

COTTON (ARIZONA ONLY)

ASPERGILLUS FLAVUS AF36 is not for sale and is only for use in an area-wide program to reduce aflatoxin contamination of cottonseed conducted in cooperation with the Arizona Cotton Research and Protection Council. ASPERGILLUS FLAVUS AF36 is for application to cotton to reduce the aflatoxin producing potential of fungi resident in agricultural fields. ASPERGILLUS FLAVUS AF 36 is a strain of Aspergillus flavus that occurs naturally on the cotton crop. When applied just prior to bloom, ASPERGILLUS FLAVUS AF36 has been shown to competitively exclude aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

DIRECTIONS FOR USE

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.

2. Best results will be achieved when the applicator is adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.

3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.

4. For best results, the crop should be furrow irrigated within seven days after application of ASPERGILLUS FLAVUS AF36.

5. Use 10 lbs. of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficiency. To avoid drift, do not apply under windy conditions.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION - Avoid breathing dust. Avoid contact with eyes and skin. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

USE DIRECTIONS

PERSONAL PROTECTIVE EQUIPMENT
APPPLICATORS AND OTHER HANDLERS MUST WEAR:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50°C (122°F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.)-Completely empty bag into application equipment. Then dispose of empty bad in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers - Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing or other human/animal uses.

WARRANTY: User assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith. In no event shall the manufacturer be liable for special, incidental or consequential damages.

PROPOSED SAMPLE LABEL

ASPERGILLUS FLAVUS AF36

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert Ingredients:	0%
Total:	100%

EPA Reg. No. 71693-

EPA Est. No. 71693-AZ-001

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive #101
Tempe, AZ 85282-3166

Net Weight 50 lbs., 1000 - 3000 lbs.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

COTTON (ARIZONA ONLY)

ASPERGILLUS FLAVUS AF36 is not for sale and is only for use in an area-wide program to reduce aflatoxin contamination of cottonseed conducted in cooperation with the Arizona Cotton Research and Protection Council. ASPERGILLUS FLAVUS AF36 is for application to cotton to reduce the aflatoxin producing potential of fungi resident in agricultural fields. ASPERGILLUS FLAVUS AF 36 is a strain of Aspergillus flavus that occurs naturally on the cotton crop. When applied just prior to bloom, ASPERGILLUS FLAVUS AF36 has been shown to competitively exclude aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

DIRECTIONS FOR USE

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.

2. Best results will be achieved when the applicator is adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.

3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.

4. For best results, the crop should be furrow irrigated within seven days after application of ASPERGILLUS FLAVUS AF36.

5. Use 10 lbs. of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficiency. To avoid drift, do not apply under windy conditions.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION - Avoid breathing dust. Avoid contact with eyes and skin. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

USE DIRECTIONS

PERSONAL PROTECTIVE EQUIPMENT
APPPLICATORS AND OTHER HANDLERS MUST WEAR:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50°C (122°F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.)-Completely empty bag into application equipment. Then dispose of empty bad in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

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WARRANTY: User assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith. In no event shall the manufacturer be liable for special, incidental or consequential damages.

PROPOSED SAMPLE LABEL

ASPERGILLUS FLAVUS AF36

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

Active ingredient: Sterile wheat seeds colonized by *Aspergillus flavus* strain AF36 (3,000 CFU/g)	100%
Inert Ingredients:	0%
Total:	100%

EPA Reg. No. 71693-

EPA Est. No. 71693-AZ-001

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive #101
Tempe, AZ 85282-3166

Net Weight 50 lbs., 1000 - 3000 lbs.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AGRICULTURAL USE REQUIREMENTS

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- Waterproof gloves
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- Dust/mist filtering respirator with MSHA/NIOSH approval prefix TC-21C

COTTON (ARIZONA ONLY)

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DIRECTIONS FOR USE

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.

2. Best results will be achieved when the applicator is adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.

3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.

4. For best results, the crop should be furrow irrigated within seven days after application of ASPERGILLUS FLAVUS AF36.

5. Use 10 lbs. of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficiency. To avoid drift, do not apply under windy conditions.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION - Avoid breathing dust. Avoid contact with eyes and skin. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

USE DIRECTIONS

PERSONAL PROTECTIVE EQUIPMENT
APPPLICATORS AND OTHER HANDLERS MUST WEAR:

- Coveralls
- Long sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
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Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. Do not store for periods greater than 12 months. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50°C (122°F). Keep product dry.

PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

CONTAINER DISPOSAL: Paper Bags (50 lbs.)-Completely empty bag into application equipment. Then dispose of empty bad in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers - Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing or other human/animal uses.

WARRANTY: User assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith. In no event shall the manufacturer be liable for special, incidental or consequential damages.

Toxicology Studies (Aspergillus flavus AF36)

Please refer to the following volumes:

a) Aspergillus flavus isolate AF36 - Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirement of a Tolerance for Aspergillus flavus for use in cotton (MRID No. 43763403).

(The above study was submitted to EPA on 8/9/95.)

b) Acute Oral Toxicity Study in Rats (MRID No. 43972403)

(The above study was submitted to EPA on 4/3/96.)

Please also refer to the following study:

c) Aspergillus flavus isolate AF36 Safety Information. This study was submitted to EPA on 6/25/98 as Volume 5 and 7 of a petition proposing an exemption from the requirement of a tolerance for Aspergillus flavus isolate AF36 use in cotton production.

Aspergillus flavus isolate AF36 - Waiver request for Toxicology Data Requirements, in regard to petition proposing an exemption of Aspergillus flavus from the requirement of a tolerance for use in cotton.

Section M Guidelines: 152A-11, 152A-12,
152A-13, 152A-14, 152A-15, 152A-16,
152A-20, 152A-21, 152A-30, 152A-31, 152A-32, 152A-33.

We request a waiver of all the toxicology data mentioned in Subdivision M, Part A published in March, 1989 that pertains to the following guidelines in Subdivision M.

Kind of Data Required	Indoor Use	Guideline Reference No.
Acute Dermal Toxicity Study	R	152A-11
Acute Pulmonary Toxicity/Pathogenicity Study	[R]	152A-12
Acute Intravenous Toxicity/Pathogenicity Study	[R]	152A-13
Primary Eye Irritation/Infection Study	[R]	152A-14
Hypersensitivity Incidents	R	152A-15
Acute Toxicity Study	CR	152A-20
Subchronic Toxicity/Pathogenicity Studies	CR	152A-21
Reproductive and Fertility Effects	CR	152A-30
Oncogenicity Study	CR	152A-31
Immunodeficiency Studies	CR	152A-32
Primate Infectivity/Pathogenicity Study	CR	152A-33

Rationale for Waiver Request of
Toxicology Data Requirements

1. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillis flavus, a saprophytic fungus, is a normal constituent of the microflora in air and soil, and is found on living and dead plant material throughout the world. A. flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403.

3. The hot desert valleys of Arizona have the reputation of being the U. S. area with conditions most conducive to Aspergillus flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop produced in Arizona. A. flavus AF36 is already present on a broad segment of the U. S. cottonseed crop and is a prominent part of the natural desert A. flavus communities. Refer to MRID No. 43763403 and Volume 5 of this submission.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to Volume 5 of this submission.

5. The amount of A. flavus AF36 being added to the soil (10 lbs. of colonized wheat seed per acre) is small in comparison to the amount of crop debris containing A. flavus that is added to the soil which includes (a) cotton foliage stalks; (b) unharvested cottonseed (i.e. bolls that are missed by the cotton harvester and spillage), and (c) gin trash which is often added back to the field and incorporated as organic matter. Refer to Volume 5 of this submission.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oil seeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403 for additional information.

7. The application of AF36 can be expected to reduce the overall toxicity of the crop by reducing aflatoxin content thus producing safer feed for animals and subsequently for humans (milk consumption). Refer to MRID No. 43763403.

8. An acute oral Toxicity Test in rats (152-10) has been conducted with Aspergillus flavus AF36. Refer to MRID No. 43972403.

9. Also refer to Volume 5 of this submission entitled "Aspergillus flavus isolate AF36-Safety Information."

Ecological Effects Data (Aspergillus flavus AF36)

Please refer to the following volume:

a) Aspergillus flavus isolate AF36 - Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirement of a Tolerance for Aspergillus flavus for use in cotton (MRID No. 43763403).

(The above study was submitted to EPA on 8/9/95.)

Please also refer to the following studies:

Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.

Aspergillus flavus isolate AF36 - Plant Studies - Request for Waiving of the Requirement for Testing.

The above studies were submitted to EPA on 6/25/98 as Volume 6 and 7 of a petition proposing an exemption from the requirement of a tolerance for Aspergillus flavus isolate AF36 use in cotton production.

Aspergillus flavus isolate AF36 - Waiver request for Non-target organism and environmental expression data requirements in regard to petition proposing an exemption of Aspergillus flavus from the requirement of a tolerance for use in cotton production.

Section M Guidelines: 154A-16, 154A-17, 154A-19, 154A-20, 154A-22.

We request a waiver of all the nontarget organism and environmental expression data mentioned in Subdivision M, Part A published in March, 1989 that pertains to the following guidelines in Subdivision M.

Guideline		
Kind of Data Required	Indoor Use	Reference No.
Avian oral	CR	152A-16
Avian Respiratory Pathogenicity Test: Tier	CR	154A-17
Freshwater Fish Toxicity and Pathogenicity Testing Tier I	CR	152A-19
Freshwater Aquatic Invertebrate Toxicity and Pathogenicity Testing: Tier I	CR	152A-20
Plant Studies: Tier I	CR	154A-22

Rationale for Waiver Request of
Non-Target Organism and Environmental Expression
Data Requirements

1. Aspergillus flavus isolate AF36 is a naturally occurring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillis flavus, a saprophytic fungus, is a normal constituent of the microflora in air and soil, and is found on living and dead plant material throughout the world. A. flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403.

3. The hot desert valleys of Arizona have the reputation of being the U. S. area with conditions most conducive to Aspergillus flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop produced in Arizona. A. flavus AF36 is already present on a broad segment of the U. S. cottonseed crop and is a prominent part of the natural desert A. flavus communities. Refer to MRID No. 43763403 and Volume 6 of this submission.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to Volume 6 of this submission.

5. The amount of A. flavus AF36 being added to the soil (10 lbs. of colonized wheat seed per acre) is small in comparison to the amount of crop debris containing A. flavus that is added to the soil which includes (a) cotton foliage stalks; (b) unharvested cottonseed (i.e. bolls that are missed by the cotton harvester and spillage), and (c) gin trash which is often added back to the field and incorporated as organic matter. Refer to Volume 6 of this submission.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oil seeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403 for additional information.

7. Exposure to A. flavus to birds or fish will not be increased by this use, since the amount of A. flavus in the environment will not change. Furthermore, cotton fields are not preferred bird habitats and feeding birds are not attracted to cotton fields. Refer to Volume 6 of this submission.

8. Also refer to Volume 6 of this submission entitled "Aspergillus flavus isolate AF36-Non Target Organism and Environmental Safety Information."

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 05-31-95

Certification with Respect to Citation of Data

Applicants Name and Address
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

EPA File Symbol/Registration Number 71693

Product Name ASPERGILLUS FLAVUS AF36

Date of Application 6/26/98

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

   [X] I am the original submitter*; or

   [ ] I have obtained the written permission of the original submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

   a. [ ] I am the original data submitter*; or

   [X] I have obtained the written permission of the original data submitter for Aspergillus Flavus AF36 (insert name of chemical), which is USDA/ARS/SRRC and IR-4 _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

   b. [ ] I have notified in writing the companies _____ (insert names of companies) for _____ (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)
   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method*).

4. [ ] I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
[signature]	DARRY ARMIJA / DIRECTOR	6-26-98

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date

EPA Form 8570-29 (Rev. 5-94) Electronic and Paper versions acceptable.
Previous editions are obsolete.

* U.S. GPO: 1995-385-820/20404

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL (Submitted by Applicant)

Aspergillus flavus isolate AF36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.

Guideline #	MRID No.
151A-11	Submitted on 6/25/98
151A-12	Submitted on 6/25/98

Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits

Guideline #	MRID No.
151A-13	Submitted on 6/25/98
151A-15	Submitted on 6/25/98

IR-4 Project, Technology Centre of New Jersey
Rutgers University, 681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Obtained from IR-4 (permission letter enclosed)

Aspergillus flavus isolate AF36 - Safety Information

Guideline #	Submitted on
152A-10, 152A-11, 152A-12, 152A-13, 152A-14, 152A-15, 152A-20, 152A-21, 152A-30, 152A-31, 152A-32, 152A-33	6/25/98*

Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.

Guideline #	Submitted on
154A-16, 154A-17, 154A-18, 154A-19, 154A-20, 154A-21, 154A-22, 154A-23, 154A-24	6/25/98*

* Studies submitted on 6/25/98 have not yet been assigned MRID numbers.

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

REGISTRANT: Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

USDA/ARS
Southern Regional Research Center
1100 Robert E. Lee Blvd.
New Orleans, LA 70179

Data obtained from USDA-ARS/Southern Regional Research Center (permission letter enclosed)

Aspergillus flavus isolate AF36 - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.

Guideline #	MRID No.
151A-10	43763401, 43990001
151A-11	43763401
151A-12	43763403

Aspergillus flavus isoalte AF36 - Analysis of Samples, Certification of Ingredigent Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.

Guideline #	MRID No.
151A-13	43763402, 43972401
151A-15	43763402, 43972401
151A-16	43763402,
151A-17	43763402, 43972401

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

REGISTRANT: Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

Data obtained from USDA-ARS/Southern Regional Research Center (permission letter enclosed)

Aspergillus flavus isolate AF36 - Plant Studies - Request for Waiving of the Requirement for Testing.

Guideline #	Submitted on
154A-4, 154A-22	6/25/98*

Aspergillus flavus isolate AF36 - Product Performance Data

Guideline #	MRID No.
156A-2, 156A-3	43763405

* Studies submitted on 6/25/98 have not yet been assigned MRID Numbers

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

REGISTRANT: Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

Data obtained from USDA-ARS/Southern Regional Research Center (permission letter enclosed)

Aspergillus flavus isolate AF36 - Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirement of a Tolerance for Aspergillus flavus for use in cotton.

Guideline #	MRID No.
152A-10, 152A-11, 152A-12	43763403

Acute Oral Toxicity Study in Rats

Guideline#	MRID No.
152A-10	43972403

Aspergillus flavus isolate AF36 - Hypersensitivity Incidents with Microbial Pest Control Agents - Statement of Finding of No Hypersensitivity.

Guideline #	MRID No.
152A-15	43763404, 43972402